As confidentially submitted to the U.S. Securities and Exchange Commission on April 2, 2018.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Aquestive Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**2834**	**82-3827296**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

30 Technology Drive
Warren, NJ 07059
(908) 941-1900
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

John T. Maxwell
Chief Financial Officer
Aquestive Therapeutics, Inc.
30 Technology Drive
Warren, NJ 07059
(908) 941-1900
(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

With copies to:

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Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Securities Exchange Act of 1934.

Large accelerated filer o	Accelerated filer o	Non-accelerated filer ☒	Smaller reporting company o
Emerging Growth Company ☒		(Do not check if a smaller reporting company)	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. o

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	**Proposed Maximum Aggregate Offering Price[(1)]**	**Amount of Registration Fee[(2)]**
Common Stock, par value $0.001 per share	$	$

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act and includes the offering price of shares that the underwriters have the option to purchase to cover over-allotments.

(2) Calculated pursuant to Rule 457(o) under the Securities Act based on an estimate of the proposed maximum aggregate offering price and includes the offering price of shares that the underwriters have the option to purchase to cover over-allotments.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the registration statement shall become effective on such date as the U.S. Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Preliminary Prospectus *Subject to Completion, dated April 2, 2018*

Shares

Aquestive Therapeutics, Inc.
Common Stock

$ Per Share

This is the initial public offering of our common stock. We are offering shares of our common stock. The initial public offering price of our common stock is expected to be between $ and $ per share.

Prior to this offering, there has been no public market for our common stock. We intend to apply for listing of our common stock on the Nasdaq Global Market under the symbol “AQST”.

We are an “emerging growth company” as defined by the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Investing in our common stock involves risks. See “Risk Factors” beginning on page 11.

	Per Share	Total
Initial public offering price	$	$
Underwriting discount[1]	$	$
Proceeds, before expenses, to Aquestive Therapeutics, Inc.	$	$

(1) We refer you to “Underwriting” beginning on page 143 of this prospectus for additional information regarding underwriting compensation.

To the extent that the underwriters sell more than shares of common stock, the underwriters have the option to purchase up to an additional shares from us at the initial public offering price less the underwriting discount.

Neither the Securities and Exchange Commission nor any state securities commission has approved of anyone’s investment in these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to the purchasers on or about , 2018.

Joint Book-Running Managers

BMO Capital Markets **RBC Capital Markets**

Co-Lead Managers

Wedbush PacGrow **JMP Securities**

Prospectus dated , 2018.

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You should rely only on the information contained in this prospectus or in any free writing prospectus we file with the U.S. Securities and Exchange Commission. Neither we nor the underwriters have authorized anyone to provide you with information other than that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell, and seeking offers to buy, common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front cover page of this prospectus, or other earlier date stated in this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common stock.

We own various U.S. federal trademark registrations and applications, and unregistered trademarks and service marks, including "Aquestive Therapeutics" and our corporate logo. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Additionally, throughout this document we use the proposed brand names of Libervant and Sympazan, which have been approved by the FDA on a preliminary basis, when referring to AQST-203 and AQST-120, respectively, despite both product candidates having yet to receive marketing approval from the FDA. All references in this prospectus to Libervant and Sympazan refer only to our product candidates and are not meant to imply FDA approval of the product candidates or their proposed brand names.

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in shares of our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. Before investing in our common stock, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes thereto and the information set forth under the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case included in this prospectus. Unless the context requires otherwise, references in this prospectus to "Aquestive," "the Company," "we," "us" and "our" refer to Aquestive Therapeutics, Inc. The consolidated financial statements included elswhere in this prospectus are those of MonoSol Rx, LLC, our predecessor entity and its consolidated subsidiary.

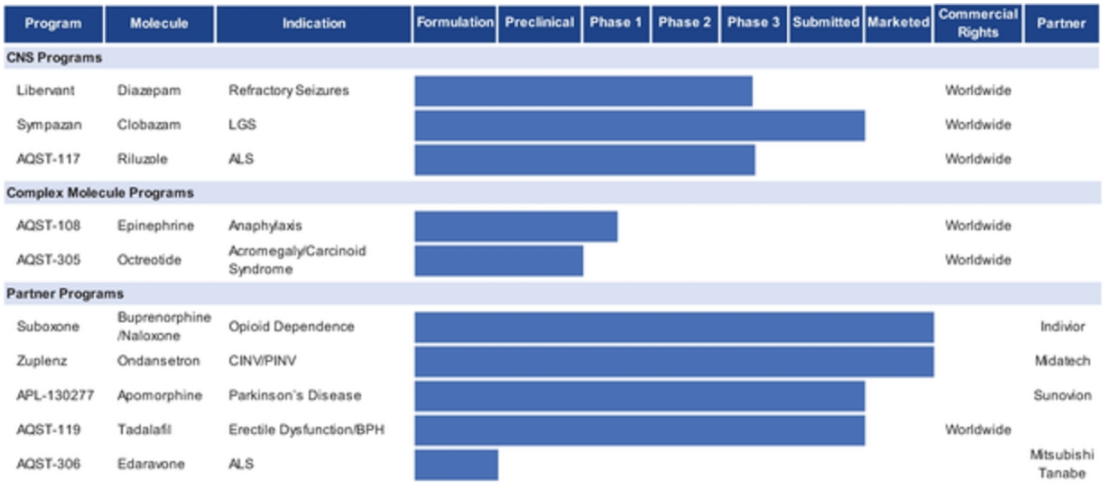
Overview

We are a specialty pharmaceutical company focused on identifying, developing and commercializing differentiated products to address unmet medical needs. We have a late-stage proprietary product pipeline focused on the treatment of diseases of the Central Nervous System, or CNS. We believe that the characteristics of these patient populations and shortcomings of available treatment options create opportunities for the development and commercialization of meaningfully differentiated medicines. Our most advanced proprietary product candidates, which we intend to commercialize ourselves, include (i) Libervant (the preliminary brand name for AQST-203), a buccally, or inside of the cheek, administered soluble film formulation of diazepam for the treatment of recurrent epileptic seizures, for which we expect to submit a New Drug Application, or NDA, in 2018; (ii) Sympazan (the preliminary brand name for AQST-120), an oral soluble film formulation of clobazam for the treatment of seizures associated with a rare, intractable form of epilepsy known as Lennox-Gastaut Syndrome, or LGS, for which we submitted an NDA in October 2017 and have been assigned an August 31, 2018 Prescription Drug User Fee Act, or PDUFA, date, which is the date the U.S. Food and Drug Administration, or FDA, expects to complete its review of our NDA, and (iii) AQST-117, an oral soluble film formulation of riluzole for the treatment of Amyotrophic Lateral Sclerosis, or ALS, for which we expect to submit an NDA in 2018. We have also developed a proprietary pipeline of complex molecule products addressing large market opportunities beyond CNS indications, which include (i) AQST-108, a sublingual film formulation of epinephrine for the treatment of anaphylaxis, for which we expect to begin additional Phase 1 trials in 2018 and (ii) AQST-305, a buccal film formulation of octreotide for the treatment of acromegaly and neuroendocrine tumors, for which we expect to begin human proof of concept trials in 2018.

In addition to these product candidates, we have a portfolio of commercialized and development-stage partnered products. These products include Suboxone, a sublingual film formulation of buprenorphine and naloxone, which is the market leader for the treatment of opioid dependence. We manufacture all of our partnered and proprietary products at our FDA and Drug Enforcement Administration, or DEA, inspected facilities and anticipate that our current manufacturing capacity is sufficient for commercial quantities of our products and product candidates currently in development. We have produced over 1.2 billion doses of Suboxone in the last four years. Our products are developed using our proprietary PharmFilm technology and know-how. Our patent portfolio currently comprises at least 200 issued patents worldwide, of which at least 40 are U.S. patents, and more than 75 pending patent applications worldwide.

Our Product Portfolio and Pipeline

The following table outlines our pipeline of product candidates:



Program	Molecule	Indication	Formulation	Preclinical	Phase 1	Phase 2	Phase 3	Submitted	Marketed	Commercial Rights	Partner
CNS Programs											
Libervant	Diazepam	Refractory Seizures								Worldwide	
Sympazan	Clobazam	LGS								Worldwide	
AQST-117	Riluzole	ALS								Worldwide	
Complex Molecule Programs											
AQST-108	Epinephrine	Anaphylaxis								Worldwide	
AQST-305	Octreotide	Acromegaly/Carcinoid Syndrome								Worldwide	
Partner Programs											
Suboxone	Buprenorphine /Naloxone	Opioid Dependence									Indivior
Zuplenz	Ondansetron	CINV/PINV									Midatech
APL-130277	Apomorphine	Parkinson's Disease									Sunovion
AQST-119	Tadalafil	Erectile Dysfunction/BPH								Worldwide	
AQST-306	Edaravone	ALS									Mitsubishi Tanabe

Proprietary CNS Product Portfolio

We have initially focused our proprietary product pipeline on certain difficult to treat CNS diseases. Our PharmFilm technology allows us to develop medicines that offer non-invasive delivery, customized suitability for patients with dysphagia, or trouble swallowing, can be administered without water and ensure consistent therapeutic dosing. We believe that these characteristics will allow us to achieve the desired patient outcomes, while potentially reducing the total cost of patient care.

The most advanced assets within our proprietary CNS portfolio are as follows:

- **Libervant** – a buccally, or inside of the cheek, administered soluble film formulation of diazepam, a benzodiazepine used as a rescue therapy for breakthrough epileptic seizures and an adjunctive therapy for use in recurrent convulsive seizures. We are developing Libervant as an alternative to Diastat (diazepam rectal gel), the current standard of care rescue therapy for patients with epilepsy, which as a rectal gel, is invasive, inconvenient, and difficult to administer. Libervant is currently completing its final clinical trials. We expect to submit an NDA for Libervant in 2018.
- **Sympazan** – an oral soluble film formulation of clobazam, a benzodiazepine used as an adjunctive therapy for seizures associated with LGS. We are developing Sympazan as an alternative to Onfi (clobazam), currently available in either tablet form or liquid suspension. LGS patients often have difficulty swallowing pills and large volume suspensions leading to uncertain and inconsistent dosing and increasing the burden of care, particularly for patients that may be combative or resistant to treatment. In clinical trials, Sympazan has demonstrated bioequivalence to Onfi. We submitted an NDA for Sympazan in October 2017 and were given a PDUFA date of August 31, 2018. If approved by the FDA, we anticipate launching Sympazan by the end of 2018.
- **AQST-117** – an oral soluble film formulation of riluzole, a small molecule glutamate antagonist used as an adjunctive therapy in the treatment of ALS, which has been shown to slow disease progression, increase lifespan and improve quality of life. However, because ALS patients typically have difficulty swallowing, tablet administration is challenging. We are developing AQST-117 as an alternative to Rilutek (riluzole), which is currently available only in tablet form in order to achieve an easier, more reliable and accurate dosing. This may allow patients to continue therapy even after their ability to swallow has become compromised. AQST-117

addresses these treatment obstacles because it is mucoadhesive and dissolves easily on the tongue without the need for water and without a substantial increase in salivary flow. In clinical trials, AQST-117 has demonstrated bioequivalence to Rilutek. We expect to submit an NDA for AQST-117 in 2018.

In March 2018, we received interim data from our adult Epilepsy Monitoring Unit, or EMU, clinical study for Libervant. The study consists of two treatment arms designed to compare the pharmacokinetics, or PK, of Libervant in subjects with epilepsy in the interictal condition, when they are not experiencing seizures, versus the ictal/peri-ictal condition, when they are experiencing seizures. Through February 2018, 12 subjects had completed the study across the two treatment arms. This represents 40% of the 30 subjects needed to complete the study. Preliminary analysis of the data indicates the following:

- A 12.5mg dose of Libervant administered during an interictal, or non-seizure, state and without regard to food (n=12 patients) provided appropriate maximal plasma concentrations of diazepam (Cmax) within 60 minutes of administration (Tmax). Furthermore, similar Cmax and Tmax levels were obtained during dosing in a peri-ictal state. We believe these results successfully demonstrate that Libervant is adequately absorbed into the blood stream regardless of whether it is applied during a seizure or normal state.
- Observed plasma levels of diazepam in patients with epilepsy were lower than plasma levels in healthy volunteers at the same dose level. This is consistent with the effects of multiple concomitant anti-epileptic drugs, or AEDs, which interact with diazepam and are commonly used by these patients.
- Based on these data, we currently anticipate that a 12.5mg dose of Libervant will be equivalent to a 17.5mg dose of Diastat. As a point of reference, our 12.5mg Libervant in patients with epilepsy had a similar Cmax to a 12.5mg dose of Diastat given to healthy volunteers with no exposure to AEDs. We believe this confirms our ability to provide an efficacious dose of Libervant at a lower dose level than Diastat.

We are in the process of requesting a face-to-face meeting with the FDA where these data, along with other clinical data, will be presented. We believe the interim data support our view that, upon the completion of our adult EMU study, we will have the necessary supporting data to submit a marketing application to the FDA.

Proprietary Complex Molecule Portfolio

We are utilizing our technology and know-how to target large market opportunities by developing orally-administered complex molecule therapies as alternatives to invasively-administered standard of care injectable therapeutics. We currently have two active complex molecule programs in clinical development, which are:

- **AQST-108** – a sublingual film formulation of epinephrine for the treatment of anaphylaxis, a severe and potentially life-threatening allergic reaction. Epinephrine is the standard of care in the treatment of anaphylaxis and is currently administered via intramuscular injection. The current market leader is EpiPen, a single-dose, pre-filled epinephrine automatic injection device. As a result of its administration via intra-muscular injection, many patients and their caregivers are reluctant to use currently available products, resulting in increased hospital visits and overall cost of care to treat anaphylactic events. We are designing AQST-108 to be the first non-injectable form of epinephrine used to treat anaphylaxis.
- **AQST-305** – a sublingual film formulation of octreotide, a small peptide that has a similar pharmacological profile to natural somatostatin, for the treatment of acromegaly, as well as severe diarrhea and flushing associated with carcinoid syndrome. Acromegaly is a hormone disorder that results from the overproduction of growth hormone in middle-aged adults. Octreotide is the standard of care for the treatment of acromegaly. The current market leader, Sandostatin (octreotide injectable suspension), is administered via deep subcutaneous or intramuscular injections once a month. This monthly treatment regimen can result in loss of

efficacy towards the end of the monthly treatment cycle. We are developing AQST-305 as a non-invasive, pain-free alternative to Sandostatin to reduce treatment burden, healthcare costs and the potential loss of efficacy over the treatment cycle.

Partnered Products

Our portfolio also includes products and product candidates that we have partnered, or will seek to partner, for commercialization. In the year ended December 31, 2017, our partnered product portfolio generated over $1 billion in revenue for our partners, resulting in $66.9 million in revenue to us. Our key partnered products include:

- **Suboxone** – a sublingual film formulation of buprenorphine and naloxone that is marketed in the United States and internationally for the treatment of opioid dependence. Suboxone was launched in 2010 in partnership with Reckitt Benckiser Pharmaceuticals, Inc., who was later succeeded to in interest by Indivior, Inc. Suboxone is the most prescribed branded product in its category with approximately 60% market share.
- **APL-130277** – a sublingual film formulation of apomorphine, a dopamine agonist in development to treat episodic off-periods in Parkinson's disease. APL-130277 is being developed as a sublingual alternative to injectable apomorphine. Sunovion Pharmaceuticals, Inc., or Sunovion, our partner and sponsor of APL-130277, submitted an NDA to the FDA on March 29, 2018.

PharmFilm – Our Oral Film Technology

We developed our PharmFilm technology to provide meaningful clinical and therapeutic advantages over other existing dosage forms and, in turn, to improve the lives of patients and caregivers.

PharmFilm is comprised of proprietary polymer compositions that serve as film formers to hold active pharmaceutical ingredients, or APIs, and excipients in place. Proprietary and patent-protected compositions, formulation and manufacturing techniques and technology are employed to ensure that the API is distributed uniformly throughout the film and that target absorption levels are achieved. Our proprietary technology and manufacturing process ensures that PharmFilm can be engineered to fit a variety of target product profiles in order to best address the unmet patient need present within specific disease states. PharmFilm, which is similar in thickness and size to a postage stamp, can be administered via buccal, sublingual or lingual oral delivery.

We believe the innovative nature of our PharmFilm drug delivery platform has the potential to offer a number of meaningful advantages to patients, caregivers and physicians compared to current standard of care therapies, including:

- preferred alternative to more invasive drugs such as injection;
- faster onset of action;
- direct absorption into the bloodstream reducing or avoiding "first pass" effects in the liver;
- reduced gastrointestinal, or GI, side effects;
- positive dosing outcomes, especially for patients with physical (*e.g.,* dysphagia) or psychological barriers to other methods of drug administration;
- stable, durable, portable and quick-dissolving (with or without water);
- customizable delivery routes for tailored PK profiles (buccal, sublingual or lingual); and
- customizable taste profiles.

Our Management Team

Our management team is a critical component to the development of our business model and the execution of our strategy. We are led by executives with an average of over 17 years of relevant senior leadership experience, including developing and commercializing branded and generic pharmaceuticals at large multinational pharmaceutical companies such as Johnson & Johnson, GlaxoSmithKline PLC and Novartis AG. Our team has significant experience in commercialization of pharmaceutical products, translational science, drug evaluation, clinical development, regulatory affairs and business development.

Our Strategy

We are a patient-centric pharmaceutical company developing and commercializing products that address unmet needs and improve the lives of patients and their caregivers. We focus on developing medicines for patient populations suffering from the shortcomings of available treatment options, which can create an opportunity for differentiated medicines. Our pipeline is initially focused on developing treatments for CNS diseases, as well as orally administered complex molecules that we believe can be alternatives to invasively-administered standard of care therapies. Our strategy leverages our global intellectual property portfolio, know-how, demonstrated research and development capabilities and proprietary manufacturing platform.

To achieve these goals, our strategy includes the following key elements:

- advance our late stage proprietary portfolio of CNS product candidates to solve critical healthcare problems and make a meaningful improvement in the lives of patients and caregivers;
- scale our commercial platform to maximize the value of our proprietary product candidates;
- exploit our technology and know-how to develop oral versions of more complex injectable drugs to address unmet patient needs;
- continue to identify product opportunities within CNS and other markets to expand our proprietary product pipeline;
- acquire products or establish partnerships to develop and market products utilizing new chemical entities; and
- continue to expand and solidify our intellectual property portfolio for our products, product candidates and manufacturing processes.

Risks Associated with Our Business

Our business is subject to numerous risks, as more fully described in the section entitled “Risk Factors” immediately following this prospectus summary. You should read these risks before you invest in our common stock. We may be unable, for many reasons, including those that are beyond our control, to implement our business strategy.

These risks include, but are not limited to, the following:

- we have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability;
- even if this offering is successful, we will need substantial additional capital to fund our operations, which may not be available on acceptable terms, if at all;
- our level of indebtedness and significant debt service obligations could constrain our ability to invest in our business and make it more difficult for us to fund our operations;
- we are dependent upon the commercial success of Suboxone and other licensing activities to generate revenue for the near future;
- we have never directly commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with collaborators;
- our commercial success depends upon attaining significant market acceptance of our products and product candidates, if approved, among patients, physicians, pharmacists and the medical community;
- if we are unable to achieve and maintain coverage and adequate reimbursement for our products or product candidates, if approved, their commercial success may be severely hindered;
- if the FDA does not conclude that our product candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product

candidates under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful;

- if we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market; and
- we rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

Corporate Information

We were originally formed in Delaware in January 2004 and until December 31, 2017, we conducted our business through MonoSol Rx, LLC, a Delaware limited liability company, or MonoSol. From the period of organization through October 31, 2017, our predecessor was a limited liability company, or LLC, treated as a partnership for income tax purposes. From November 1, 2017 through December 31, 2017, MonoSol elected to be taxed as a C corporation. On January 1, 2018, MonoSol converted from a Delaware LLC into a Delaware corporation pursuant to a statutory conversion and changed its name to Aquestive Therapeutics, Inc. In a corporate reorganization conducted following the conversion of MonoSol into a Delaware corporation, the holders of units of MonoSol contributed their interests in MonoSol to Aquestive Partners, LLC in exchange for identical interests in Aquestive Partners, LLC and following such exchange Aquestive Partners, LLC became the parent and sole stockholder of Aquestive Therapeutics, Inc. Upon consummation of this offering, our shares held by Aquestive Partners, LLC will be distributed to the holders of interests in Aquestive Partners, LLC in exchange for such interests, and Aquestive Partners, LLC will be liquidated. Except as disclosed in this prospectus, the consolidated financial statements and selected historical consolidated financial data and other financial information included in this prospectus are those of MonoSol prior to the conversion into Aquestive Therapeutics, Inc.

Our principal executive office is located at 30 Technology Drive, Warren, New Jersey 07059, and our telephone number is (908) 941-1900. Our corporate website address is www.aquestive.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

Implications of Being an Emerging Growth Company

We are an “emerging growth company,” as defined in Section 2(a) of the Securities Act of 1933, as amended, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we are eligible to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies,” including, but not limited to:

- not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002;
- being permitted to present only two years of audited financial statements and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We have taken advantage of some of the reduced reporting burdens in this prospectus and may take advantage of additional exemptions in the future. Accordingly, the information contained herein may be different than the information provided by other public companies. We do not know if some investors will

find our shares less attractive as a result of our utilization of these or other exemptions. The result may be a less active trading market for our shares and our share price may be more volatile.

In addition, Section 107 of the JOBS Act also provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. As an emerging growth company, we have elected to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public emerging growth companies.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the consummation of this offering, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded $700.0 million as of the last day business day of our most recently completed second fiscal quarter, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. Please note any references herein to “emerging growth company” shall have the meaning associated with it in the JOBS Act.

THE OFFERING

Shares of common stock offered by us	shares
Shares of common stock to be outstanding after this offering	shares
Over-allotment option to purchase additional shares	shares
Use of proceeds	We estimate that the net proceeds from this offering will be $ million, or approximately $ million if the underwriters exercise their over-allotment option in full, assuming an initial public offering price of $ per share (the mid-point of the price range set forth on the cover page of this prospectus), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents and cash generated from existing partnerships, (i) to fund pre-launch commercialization investments for our epilepsy products, Libervant and Sympazan, as well as AQST-117, (ii) to fund the commencement of our clinical trials for our complex molecules AQST-108 and AQST-305, (iii) to identify our new pipeline candidates in epilepsy and other CNS diseases, and (iv) for general corporate purposes, including working capital and capital expenditures. See "Use of Proceeds" on page 54.
Proposed Nasdaq Global Market symbol	"AQST"
Risk factors	You should read the "Risk Factors" section of this prospectus for a discussion of certain of the factors to consider carefully before deciding to purchase any shares of our common stock.

The number of shares of our common stock to be outstanding after this offering is based on shares of common stock outstanding as of December 31, 2017 (on a pro forma basis), and excludes:

- shares of common stock issuable upon the exercise of warrants to purchase 4.5% of our common stock on a fully diluted basis through August 16, 2023 at an exercise price of $0.01 per share; and
- shares of common stock reserved for future issuance under our 2018 Equity Incentive Plan, or the 2018 Plan.

Unless otherwise indicated, all information contained in this prospectus assumes:

- a for reverse stock split of our common stock effected on , 2018;
- no exercise by the underwriters of their option to purchase an additional shares of our common stock; and
- no issuance or exercise of stock options or warrants on or after December 31, 2017.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following table summarizes our historical financial data as of, and for the periods ended on, the dates indicated. We have derived the statements of operations data for the years ended December 31, 2017 and 2016 and balance sheet data as of December 31, 2017 and 2016 from our audited consolidated financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. The summary of our financial data set forth below should be read together with our consolidated financial statements, and the related notes thereto and "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this prospectus.

	Year Ended December 31,	
	2017	2016
(In thousands, except per membership interest and per share data)		
Statements of Operations Data:		
Revenues	$ 66,918	$ 51,785
Costs and expenses:		
Manufacture and supply	19,820	16,378
Research and development	22,133	15,450
Selling, general and administrative	25,078	20,804
Total costs and expenses	67,031	52,632
Operating loss	(113)	(847)
Other expenses:		
Interest expense	(7,707)	(6,143)
Loss on extinguishment of debt	—	(757)
Loss on impairment of investment	—	(1,006)
Change in fair value of warrant	(1,123)	(750)
Other income (expense)	—	(99)
Net loss before income taxes	(8,943)	(9,602)
Income taxes	—	—
Net loss	(8,943)	(9,602)
Dividends on redeemable preferred interests	(2,480)	(2,342)
Net loss attributable to members' interest	(11,423)	(11,944)
Comprehensive loss	$ (11,423)	$ (11,944)
Net loss per membership interest	$ (0.09)	$ (0.10)
Weighted-average number of membership interests outstanding used to compute net loss per share membership interests	121,228,353	118,785,104
Unaudited pro forma net loss[1]	$ (8,943)	
Unaudited pro forma net loss per share of common stock	$ (0.04)	
Unaudited pro forma weighted-average number of shares of common stock outstanding used to compute net loss per share of common stock[1]	246,768,153	

(1) See Note 2 of our notes to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the pro forma net loss, net loss per share and the weighted-average number of shares used in the computation of the per share amounts.

(In thousands)	As of December 31, 2017		
	Actual	Pro Forma[1]	Pro Forma As Adjusted[2][3]
		(unaudited)	
Balance Sheet Data:			
Cash and cash equivalents	$ 17,379	$ 17,379	
Working capital[4]	12,813	12,813	
Total assets	43,116	43,116	
Total debt	45,507	45,507	
Redeemable preferred interests and accrued dividends	42,101	—	
Accumulated deficit	(120,093)	(117,613)	
Members' deficit	(68,596)	(26,495)	

(1) The pro forma column reflects (i) the automatic conversion of all of MonoSol's Preferred A interests, Preferred A-1 interests, Preferred A-2 interests and Preferred A-3 interests into an aggregate of 125,539,800 shares of Aquestive common stock upon the consummation of this offering and (ii) the automatic conversion of 121,228,353 of MonoSol's common interests into Aquestive common stock upon the consummation of this offering.

(2) The pro forma as adjusted column reflects the pro forma adjustments discussed above and the sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, the mid-point of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the mid-point of the price range set forth on the cover page of this prospectus, would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity on a pro forma as adjusted basis by approximately $ million, assuming that the number of shares offered by Aquestive, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase (decrease) of shares in the number of shares offered by Aquestive would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity on a pro forma as adjusted basis by approximately $ million, assuming that the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by Aquestive. The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

(4) Working capital is defined as current assets less current liabilities. See MonoSol's consolidated financial statements for additional information regarding our current assets and current liabilities.

RISK FACTORS

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this prospectus, before deciding to invest in our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Financial Condition and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We have a limited operating history. To date, we have focused primarily on developing a broad product portfolio and have obtained regulatory approval for two of our products: Suboxone, the first sublingual film product for the treatment of opioid dependence, and Zuplenz, the first approved prescription oral soluble film for the prevention of chemotherapy-induced, radiotherapy-induced, and postoperative nausea and vomiting. Some of our product candidates will require substantial additional development time and resources before we would be able to receive regulatory approvals, implement commercialization strategies and begin generating revenue from product sales. We may not generate significant revenue from sales of our product candidates in the near term, if ever. We have incurred losses of $8.9 million and $9.6 million for the years ended December 31, 2017 and 2016, respectively. As of December 31, 2017, we had an accumulated deficit of $120.1 million from inception.

We have devoted most of our financial resources to product development. To date, we have financed our operations primarily through the sale of equity and debt securities and from revenues from certain partnerships we have entered into with respect to our products. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenue. To date, only two of our products, Suboxone and Zuplenz, have been commercialized, and if our product candidates are not successfully developed or commercialized, or if revenue is insufficient following marketing approval of such product candidates, we will not achieve profitability and our business may fail.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to fully predict the timing or amount of our expenses, but we expect to continue to incur substantial expenses, which we expect to increase as we expand our development activities and product portfolio. Some of the expenses we expect to continue to incur include:

- conducting clinical trials of our product candidates;
- seeking regulatory approval for any of our product candidates that successfully complete clinical development;
- commercialization activities, including product sales, marketing, manufacturing and distribution, for our products, if approved;
- maintaining, expanding and protecting our intellectual property portfolio;
- acquiring or in-licensing new technologies or development-stage or approved products;
- adding clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our transition to being a public company; and
- experiencing any delays or encountering any issues with any of the above, including, but not limited to, failed trials, complex results, safety issues or other regulatory challenges.

As a result of the foregoing, we expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future, which may increase compared to past periods.

Even if this offering is successful, we will need substantial additional capital to fund our operations, which may not be available on acceptable terms, if at all. If we are unable to raise capital when needed, we may need to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates.

Our operations have consumed substantial amounts of cash. We had $17.4 million in cash and cash equivalents as of December 31, 2017. Currently, our cash equivalents have a maturity of three months or less. We have no committed sources of capital and our borrowing capability under our loan agreement, or the Loan Agreement, with Perceptive Credit Opportunities Fund, LP, or Perceptive, is fully drawn.

We believe that the net proceeds from this offering, combined with our existing cash and cash equivalents and expected revenue from our partnered product activities, will be sufficient to fund our operations at least through the next 24 months of operations, including our planned investments in the pre-launch commercialization of our late stage CNS product candidates, research and development investments in our complex molecule product pipeline candidates, capital expenditures and investments in new product candidates in epilepsy and other CNS diseases. We have based this estimate on assumptions that could change, and we could utilize our available financial resources sooner than we currently expect. We expect to continue to spend substantial amounts to commercialize our epilepsy products, Libervant and Sympazan, our ALS product, AQST-117, and our other proprietary product candidates. Based on our current operating budget and business plan, we will need to raise substantial additional financing by various means, including, among others, through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. Our existing resources may not be adequate to permit us to complete clinical development of our product candidates or fund our operations over the longer term. We may need to secure significant additional resources to complete such development and to support our continued operations. We are exploring a variety of funding alternatives, including both dilutive and non-dilutive financing options and strategic partnerships.

Our estimate of the period of time through which our financial resources will be adequate to support our operations is based on assumptions that may prove to be wrong, and we could deplete our available capital resources sooner than we currently expect. In addition, our operating plan and budget could change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, whether through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches.

We have historically relied upon sales of Suboxone and Zuplenz, our two commercialized partnered products, milestone payments, fees from co-development and research services, fees from licensed proprietary technologies and patent rights, and royalties based on specified product sales, together with private sales of equity or debt securities, to fund our operations. Delays in obtaining funding could adversely affect our ability to develop and commercially introduce products, if approved, and cause us to be unable to comply with our obligations. Even if we believe we have sufficient capital for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates.

Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that would likely result in our stockholders losing some or all of their investment in us.

We may sell additional equity or incur debt to fund our operations, which may result in dilution to our stockholders, including purchasers of shares of common stock in this offering, and impose restrictions on our business.

We do not have any committed external source of funds other than potential milestone payments and royalties under certain of our collaboration agreements. Until such time, if ever, as we can generate sufficient revenue to fully fund our operations, we may seek additional capital through a public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financings may be coupled with an equity component, such as warrants to purchase shares of our common stock, which could also result in dilution of existing stockholders' ownership. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business and may result in liens being placed on our assets and intellectual property. If we were to default on such indebtedness, we could lose such assets and intellectual property.

If we raise additional funds through collaborations, or strategic alliance, marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates or future revenue streams or grant licenses on terms that are not favorable to us.

Even if we are able to generate revenues from our operations in the future, our revenues and operating income could fluctuate significantly.

Even if we are able to generate future revenues, our operating income, and results may vary significantly from year-to-year and quarter-to-quarter. Variations may result from, among other factors:

- the timing of FDA or any other regulatory authority approvals;
- the timing of process validation for particular product candidates;
- the timing of product launches and market acceptance of such products launched;
- changes in the amount we spend to research, develop, acquire, license or promote new product candidates;
- the outcome of our research, development and clinical trial programs;
- serious or unexpected health or safety concerns related to our product candidates;
- the introduction of new products by others that render our product candidates obsolete or noncompetitive;
- our ability to maintain selling prices and gross margins on our product candidates;
- our ability to comply with complex governmental regulations applicable to many aspects of our business;
- changes in coverage and reimbursement policies of health plans and other health insurers, including changes to Medicare, Medicaid and similar government healthcare programs;
- increases in the cost of raw materials used to manufacture our product candidates;
- manufacturing and supply interruptions, including product rejections or recalls due to failure to comply with manufacturing specifications;
- timing of revenue recognition related to our collaboration agreements;
- our ability to protect our intellectual property and avoid infringing the intellectual property of others; and
- the outcome and cost of possible litigation with third parties.

Our level of indebtedness and significant debt service obligations could constrain our ability to invest in our business and make it more difficult for us to fund our operations.

We have, and after the consummation of this offering will continue to have, substantial debt and substantial debt service obligations. At December 31, 2017, we had an aggregate principal amount of $50.0 million of outstanding indebtedness. In the future, we may need to borrow additional funds.

Because of our indebtedness:

- we may have difficulty satisfying our obligations with respect to our existing indebtedness including the repayment of such indebtedness;
- we may have difficulty obtaining financing in the future for working capital, capital expenditures, acquisitions or other purposes;
- we will need to use a substantial portion of our available cash flow to pay interest and principal on our debt, which will reduce the amount of money available to finance our operations and other business activities;
- we may be more vulnerable to general economic downturns and adverse industry conditions;
- if cash flows from product sales are insufficient to satisfy our obligations with respect to our existing indebtedness, we may be forced to sell assets or seek additional capital, which we may not be able to accomplish on favorable terms, if at all;
- we could be limited in our flexibility in planning for, or reacting to, changes in our business and in our industry in general;
- we could be placed us at a competitive disadvantage compared to our competitors that have less debt;
- our failure to comply with the financial and other restrictive covenants in our debt instruments which, among other things, require us to maintain specified financial covenants and limit our ability to incur debt and sell assets, could result in an event of default that, if not cured or waived, could have a material adverse effect on our business or prospects; and
- our tangible and intangible assets, including our intellectual property are subject to first priority liens and may be used to satisfy our outstanding debt.

We intend to satisfy our current and future debt service obligations with our existing cash and cash equivalents. However, we may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under our Loan Agreement or any other debt instruments we may enter into. Failure to make payments or comply with other covenants under our existing credit facility or such other debt instruments could result in an event of default and acceleration of amounts due, which could have a material adverse effect on our business, financial condition and results of operations.

We are dependent upon the commercial success of Suboxone and other licensing activities to generate revenue for the near future.

Although we are in the process of testing and developing proprietary product candidates and may seek to acquire rights in other approved drugs, we anticipate that our ability to generate revenue and to become profitable in the near future will depend upon the continued commercial success of our only approved partnered products, Zuplenz and Suboxone, as well as our other licensing and partnered development activities. There is no assurance that we will become commercially successful. If Zuplenz and Suboxone are not commercially successful, we cannot continue to generate licensing revenues and we have not received approval for any other of our product candidates, we may not be able to generate any royalties or product revenue, as the case may be, for those products or proprietary our product candidates at all. Moreover, any delay or setback in the development of any product candidate could materially adversely affect our business and cause the price of our common stock to fall.

Additionally, we are currently named as a defendant in litigation brought against us and Indivior. Such litigation involves allegations that defendants engaged in conduct intended to interfere with the introduction of generic drug products based on our product, Suboxone, to the marketplace. The Company

denies any wrongdoing and is defending that litigation, but depending on the outcome of the litigation, whether or not any remedies are entered against us or Indivior and, if so, what those remedies are, it could affect our ability to recognize revenues from Suboxone. For more information, please see the section titled “Business – Legal Proceedings.” Moreover, any delay or setback in the development of any product candidate could materially adversely affect our business and cause the price of our common stock to fall.

Risks Related to Commercialization of Our Products and Product Candidates

We cannot be certain that we will be able to successfully develop our product candidates or obtain regulatory approval for our product candidates.

We currently have nine product candidates in clinical development. Our business depends primarily on the successful clinical development, regulatory approval and commercialization of our product candidates. Before our product candidates can be marketed, the FDA and other comparable foreign regulatory agencies must approve our NDA or comparable regulatory submissions. Even after successful completion of clinical testing, there is a risk that the FDA may request further information from us, disagree with our findings or otherwise undertake a lengthy review of our submission. Even if the FDA approves our NDA, we may be unable to successfully commercialize our product candidates.

It is possible that the FDA will not approve any application that we may submit or our product candidates may not obtain appropriate regulatory approvals necessary for us to commence clinical trials for our product candidates. Any delay or failure in obtaining required approvals could have a material adverse effect on our business. This process can take many years and will likely require the expenditure of substantial resources beyond the proceeds we currently have on hand.

Even if we obtain approval from the FDA and comparable foreign regulatory authorities for our current and future product candidates, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of that product candidate or any other product candidate that we may in-license, develop or acquire in the future.

We have never directly commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with collaborators.

We have relied on our third-party collaborators to commercialize our products, Suboxone and Zuplenz. Thus, we do not have direct experience in commercializing a product candidate. To achieve commercial success of our product candidates, if any are approved, we will have to develop our own sales, marketing and supply capabilities or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates on our own include: recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment and resources, is time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States or other key global markets. We also intend to enter into strategic partnerships with third parties to commercialize our product candidates outside of the United States. We may have difficulty establishing relationships with third parties on terms that are acceptable to us, or in all of the regions where we wish to commercialize our products, or at all. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them.

Our commercial success depends upon attaining significant market acceptance of our products and product candidates, if approved, among patients, physicians, pharmacists and the medical community.

It is possible that we may not complete development of our product candidates or obtain regulatory approval. Even if we do complete development and obtain regulatory approval for our product candidates, our product candidates may not gain market acceptance among patients, physicians, pharmacists, the medical community or third-party payors, which is critical to commercial success. Market acceptance of our products and any product candidate for which we receive approval depends on a number of factors, including:

- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- the potential and perceived advantages of such product candidate over alternative treatments;
- favorable pricing and the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- the availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
- relative convenience and ease of administration;
- any negative publicity related to our or our competitors' products that include the same active ingredient;
- the prevalence and severity of adverse side effects, including limitations or warnings contained in a product's FDA-approved labeling; and
- the effectiveness of sales and marketing efforts.

Even if a potential product displays a favorable efficacy and safety profile in clinical trials, market acceptance of the product will not be known until after it is launched. If our products or product candidates, if approved, fail to achieve an adequate level of acceptance by physicians, nurses, pharmacists, patients and the medical community, we will be unable to generate significant revenues, and we may not become or remain profitable.

Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon product candidates, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects that may be caused by our product candidates could result in the delay, suspension or termination of clinical trials by us, our collaborators, the FDA or other regulatory authorities for a number of reasons. For example, to date, patients treated with Libervant have experienced drug-related side effects including somnolence, or a state of strong desire for sleep, or sleeping for unusually long periods. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. If we elect or are required to delay, suspend or terminate any clinical trial for any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed or eliminated. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

We could incur substantial costs and disruption to our business and delays in the launch of our product candidates if our competitors and/or collaborators bring legal actions against us, which could harm our business and operating results.

We cannot predict whether our competitors or potential competitors, some of whom we collaborate with, may bring legal actions against us based on our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, claiming, among other things, infringement of their intellectual property rights, breach of contract or other legal theories. If we are forced to defend any such lawsuits, whether they are with or without merit or are ultimately determined in our favor, we may face costly litigation and diversion of technical and management personnel. These lawsuits could hinder our ability to enter the market early with our product candidates and thereby hinder our ability to influence usage patterns when fewer, if any, of our potential competitors have entered such market, which could adversely impact our potential revenue from such product candidates. Some of our competitors have substantially greater resources than we do and could be able to sustain the cost of litigation to a greater extent and for longer periods of time than we could. Furthermore, an adverse outcome of a dispute may require us: to pay damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed a party's patent or other intellectual property rights; to cease making, licensing or using products that are alleged to incorporate or make use of the intellectual property of others; to expend additional development resources to reformulate our products or prevent us from marketing a certain drug; and to enter into potentially unfavorable royalty or license agreements in order to obtain the rights to use necessary technologies. Royalty or licensing agreements, if required, may be unavailable on terms acceptable to us, or at all.

Guidelines and recommendations published by government agencies can reduce the use of our product candidates.

Government agencies promulgate regulations and guidelines applicable to certain drug classes which may include our products and product candidates that we are developing. Recommendations of government agencies may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Regulations or guidelines suggesting the reduced use of certain drug classes which may include our products and product candidates that we are developing or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our product candidates or negatively impact our ability to gain market acceptance and market share.

We face significant competition from other specialty pharmaceutical and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The specialty pharmaceutical industry is intensely competitive and subject to rapid and significant technological change. We expect to have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug administration technologies that are more effective or less than product candidate that we are currently developing or that we may develop. In addition, our competitors may file citizen petitions with the FDA in an attempt to persuade the FDA that our products, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety of our products and product candidates, including as relative to marketed products and product candidates in development by third parties;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- the ability to maintain a good relationship with regulatory authorities;
- the ability to commercialize and market any of our product candidates that receive regulatory approval;
- the price of our products, including in comparison to branded or generic competitors;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- the ability to protect intellectual property rights related to our products and product candidates;
- the ability to manufacture on a cost-effective basis and sell commercial quantities of our products and product candidates that receive regulatory approval; and
- acceptance of any of our products and product candidates that receive regulatory approval by physicians and other healthcare providers.

If our competitors market products that are more effective, safer or less expensive than our product candidates, or that reach the market sooner than our product candidates, we may enter the market too late in the cycle and may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because we have limited research and development capabilities, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

If we are unable to achieve and maintain coverage and adequate reimbursement for our products or product candidates, if approved, their commercial success may be severely hindered.

Our ability to commercialize our product candidates successfully will depend in part on the extent to which coverage and adequate reimbursement are available for our product candidates, once approved, from third-party payors, including governmental healthcare programs such as Medicare and Medicaid, commercial health insurers and managed care organizations, and how quickly we obtain such coverage and reimbursement, if we are able to obtain it at all. Third-party payors determine which medications they will cover and establish reimbursement levels. Reimbursement decisions by third-party payors depend upon a number of factors, including each third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- appropriate and medically necessary for the specific condition or disease;
- cost effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for our product candidates from third-party payors may be a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data, including results from expensive pharmacoeconomic studies, beyond the data required to obtain marketing approval, to each third-party payor. There is no guarantee that we will be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement.

Third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for medical products and services. Third-party payors may deny reimbursement for covered products if they determine that a medical product was not used in accordance with third-party payor coverage policies, such as required procedures for cost-effective diagnosis methods and other conditions that must be met before the third-party payor will provide coverage for use of a

product. For example, insurers may establish a “step-edit” system that requires a patient to first use a lower price alternative product prior to becoming eligible for reimbursement of a higher price product. Third-party payors also may refuse to reimburse for drugs, procedures and devices deemed to be experimental, or that are prescribed for an unapproved indication. In addition, third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Further, some third-party payors are the challenging the prices charged for medical products and may impose price controls or require that drug companies provide them with predetermined discounts from list prices.

The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Levels of reimbursement may also decrease in the future, and future legislation, regulation or reimbursement policies of third-party payors may adversely affect the reimbursement available for and the pricing of our product candidates, once approved, which in turn, could negatively impact the demand for our product candidates. If patients are not adequately reimbursed for our product candidates, they may reduce or discontinue purchases of it, which would result in a significant shortfall in achieving revenue expectations and negatively impact our business, prospects and financial condition.

Our relationships with customers, physicians, and third-party payors will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may subject us to various federal and state fraud and abuse laws and other health care laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations promulgated thereunder. These laws will impact, among other things, our clinical research program and our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers on the other. The Patient Protection and Affordable Care Act, as amended, or the PPACA, amended the intent requirement of the federal Anti-Kickback Statute. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it;
- federal civil and criminal false claims laws, including, without limitation, the False Claims Act, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. The PPACA provides, and recent government cases against pharmaceutical and medical device manufacturers support, the view that federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may implicate the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (*e.g.,* public or private);

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization on entities subject to the rule, such as health plans, health care clearinghouses and certain health care providers, and their respective business associates who provide services involving the creation, use or disclosure of HIPAA protected health information;
- federal transparency laws, including the federal Physician Payments Sunshine Act, which is part of the PPACA, that require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to: (i) payments or other "transfers of value" made to physicians and teaching hospitals; and (ii) ownership and investment interests held by physicians and their immediate family members, with such information being made publicly available through a searchable website;
- state and foreign law equivalents of each of the above federal laws; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or pricing information; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; and state and local laws that require the registration of pharmaceutical sales representatives; and
- state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Recently enacted and future healthcare reform legislation or regulation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and may adversely affect the prices we, or they, may obtain and may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other

things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any future collaborators, to profitably sell any products for which we, or they, obtain marketing approval. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for any approved products.

In March 2010, President Obama signed into law the PPACA. Among the provisions of the PPACA of importance to our business, including, without limitation, our ability to commercialize and the prices we may obtain for any of our product candidates and that are approved for sale, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee does not apply to sales of certain products approved exclusively for orphan indications;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;
- addition of more entity types eligible for participation in the Public Health Service the 340B drug pricing program, or the 340B program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; the Bipartisan Budget Act of 2018, or BBA, among other things, increased the manufacturer's subsidy under this program from 50% to 70% of the negotiated price, beginning in 2019;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (*i.e.,* automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation, including the BBA, extended the 2% reduction, on average, to 2027, subject to additional Congressional action. Sequestration may result in additional reductions in Medicare and other healthcare funding and, if we obtain regulatory approvals, may otherwise affect the prices we may obtain for our product candidates or the frequency with which our product candidates may be prescribed or used if approved. Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which will be fully implemented in 2019. At this time, it is unclear how the introduction of the Medicare quality payment program will impact overall physician reimbursement.

Further, legislative changes to or regulatory changes under the PPACA remain possible and appear likely in the 115th U.S. Congress and under the Trump administration. The nature and extent of any legislative or regulatory changes to the PPACA, including repeal and replacement initiatives, are uncertain at this time. It is possible that the PPACA repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017, or the TCJA, which was recently signed into law by President Trump, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the BBA, among other things, amends the PPACA, starting January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." The scope of potential future legislation to modify or repeal and replace the PPACA provisions is highly uncertain in many respects. We continue to evaluate the potential impact of the PPACA and its possible repeal or replacement on our business.

The costs of prescription pharmaceuticals in the United States have also been the subject of considerable discussion in the United States, and members of Congress and the administration have stated that they will address such costs through new legislative and administrative measures. This focus has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates to other available product candidates. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, the TCJA was enacted. The TCJA is major tax legislation that, among other things, contains significant changes to corporate taxation, including reducing the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; limiting the tax deduction for interest expense; limiting the

deduction for net operating losses and eliminating net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such tax losses may be carried forward indefinitely); eliminating certain requirements of the PPACA, including the individual mandate; and modifying or repealing many business deductions and credits, including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as “orphan drugs”. We continue to examine the impact this tax reform legislation may have on our business. However, the effect of the TCJA on us and our affiliates, whether adverse or favorable, is uncertain and may not become evident for some period of time. You are urged to consult your tax adviser regarding the implications of the TCJA on an investment in our common stock.

Even though we have obtained orphan drug designation for Libervant and AQST-117 in the United States, we may not obtain or maintain orphan drug exclusivity for these or other product candidates, and we may not obtain orphan drug designation or exclusivity for any of our other product candidates or indications.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same disease for seven years. Orphan drug exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation must be requested before submitting an application for marketing approval.

We obtained orphan drug designation in the United States for Libervant for the treatment of selected, refractory patients with epilepsy who are on stable regimens of antiepileptic drugs, or AED, and who require intermittent use of diazepam to control bouts of increased seizure activity, or acute repetitive seizures, and for AQST-117 for the treatment of amytrophic lateral sclerosis, or ALS. A company that first obtains FDA approval for a designated orphan drug for the designated rare disease or condition receives orphan drug marketing exclusivity for that drug for the designated disease for a period of seven years in the United States. This orphan drug exclusivity prevents the FDA from approving another application to market a drug containing the same active moiety for the same orphan indication, except in very limited circumstances, including when the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation.

Even though we have received orphan drug designation for Libervant and for AQST-117, we may not be the first to obtain marketing approval for the orphan-designated indication due to the uncertainties associated with developing product candidates. For example, other pharmaceutical companies developing diazepam have obtained orphan drug designation for their product candidates for an acute repetitive seizures indication using other routes of administration, such as intranasal and subcutaneous. While there can be no assurance, we believe that our Libervant is further along in development than these other companies’ versions of diazepam. However, if any of these other pharmaceutical companies obtains approval of an NDA for its formulation of diazepam for the management of acute repetitive seizures before we are able to receive approval of Libervant for the same indication, we would be barred from marketing Libervant in the United States during the seven-year orphan drug exclusivity period, unless we could demonstrate that Libervant is clinically superior to the approved diazepam product. In addition, in order to obtain our own period of marketing exclusivity, we would need to demonstrate that Libervant is clinically superior to any other diazepam products approved for the same indication, including Diastat.

Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition or a drug with the same active moiety can be approved for a different

indication. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, even if we intend to seek orphan drug designation for other product candidates or indications, we may never receive such designations or obtain orphan drug exclusivity.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party contract research organizations, or CROs, to monitor and manage data for our preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with FDA laws and regulations regarding current good clinical practice, or GCP, which are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization, or ICH, guidelines for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under the current good manufacturing practice, or cGMP, regulations. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. In addition, portions of the clinical trials for our product candidates are expected to be conducted outside of the United States, which will make it more difficult for us to monitor CROs and perform visits of our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCP. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process.

Some of our CROs have an ability to terminate their respective agreements with us if, among other reasons, it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on limited sources of supply for our thin film foil, and any disruption in the chain of supply may impact production and sales and cause delay in developing and commercializing our Proprietary PharmFilm Technology product candidates.

We currently have relationships with only one third party for the manufacture of our thin film foil. Because of the unique equipment and process for manufacturing our thin film foil, transferring manufacturing activities for our foil to an alternate supplier would be a time-consuming and costly endeavor, and there are only a limited number of manufacturers that we believe are capable of performing this function for us. Switching thin film foil suppliers may involve substantial cost and could result in a delay in our desired clinical and commercial timelines. If any of our thin film foil manufacturers breaches or terminates their agreements with us, we would need to identify an alternative source for the thin film foil manufacture and supply of foil to us for the purposes of our development and commercialization of the applicable products. Identifying an appropriately qualified source of alternative thin film foil supply for any one or more of these product candidates could be time consuming, and we may not be able to do so without incurring material delays in the development and commercialization of our product candidates, which could harm our financial position and commercial potential for our products. Any alternative thin film foil vendor would also need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if we appoint a new manufacturer for supply of our product candidates that differs from the manufacturer used for clinical development of such product candidates. For our other product candidates, we expect that only one supplier will initially be qualified as a vendor with the FDA. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of components and active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

We rely on third parties to manufacture active pharmaceutical ingredients, or API, for our product candidates, and we intend to rely on third parties to manufacture the API for any other approved products. The commercialization of any of our products could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of API or fail to do so at acceptable quality levels or prices or fail to maintain or achieve satisfactory regulatory compliance.

We currently rely, and expect to continue to rely, on third parties to manufacture API for our product candidates, and control only certain aspects of their activities.

Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it could delay our proprietary product candidate programs and commercialization activities. Our reliance on these third parties reduces our control over these activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards and any applicable trial protocols. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, clinical trials required to support future regulatory submissions and approval of our product candidates.

Our products and product candidates are highly reliant on very complex sterile techniques and personnel aseptic techniques. The facilities used by our third-party API manufacturers to manufacture our products and product candidates must maintain a compliance status acceptable to the FDA or other applicable regulatory authorities pursuant to inspections that will be conducted after we submit our NDA to the FDA. If any of our third-party API manufacturers cannot successfully manufacture material that conforms to our specifications and the applicable regulatory authorities' strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain regulatory approval for the manufacturing facilities. In addition, we have no control over the ability of third-party API manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Further, as we scale up

manufacturing of our product candidates and conduct required stability testing, product, packaging, equipment and process-related issues may require refinement or resolution in order for us to proceed with our planned clinical trials and obtain regulatory approval for commercialization of our product candidates. In the future, for example, we may identify impurities in the product manufactured for us for commercial supply, which could result in increased scrutiny by the regulatory agencies, delays in our clinical program and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for our product candidates. If the FDA or any other applicable regulatory authority does not approve these facilities for the manufacture of our products or if they withdraw any such approval in the future, or if our suppliers or third-party manufacturers decide they no longer want to manufacture our products, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products or product candidates.

More generally, API manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Additionally, our API manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to make product candidates available for clinical trials and development purposes or to further commercialize any of our product candidates in the United States would be jeopardized. Any delay or interruption in our ability to meet commercial demand may result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for approved products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Additionally, if supply from one approved API manufacturer is interrupted, there could be a significant disruption in commercial supply. Regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

The occurrence of any of these factors could have a material adverse effect on our business, results of operations, financial condition and prospects.

The design, development, manufacture, supply, and distribution of our product candidates is highly regulated and technically complex.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP and equivalent foreign standards. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. The development, manufacture, supply, and distribution of our other product candidates, is highly regulated and technically complex. We, along with our third-party providers, must comply with all applicable regulatory requirements of the FDA and foreign authorities.

We, or our API and component manufacturers, must supply all necessary documentation in support of our regulatory filings for our product candidates on a timely basis and must adhere to the FDA's good laboratory practices, or GLP, and cGMP regulations enforced by the FDA through its facilities inspection program, and the equivalent standards of the regulatory authorities in other countries. Any failure by our third-party API or component manufacturers to comply with cGMP or failure to scale-up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party API and component manufacturers must also pass a pre-approval inspection for compliance with the applicable

regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities in any country may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities and quality systems do not pass a pre-approval plant inspection, FDA approval of our product candidates, or the equivalent approvals in other jurisdictions, will not be granted.

Regulatory authorities also may, at any time following approval of a product for sale, inspect our manufacturing facilities or those of our third-party suppliers or contractors. If any such inspection identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. If we or any of our third-party API or component manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending NDA for a new drug product or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

We may not be successful in establishing development and commercialization collaborations, which could adversely affect, and potentially prohibit, our ability to develop our product candidates.

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we are exploring collaborations with third parties outside of the United States that have more resources and experience. For example, we are exploring selective partnerships with third parties for development and commercialization of our product candidates outside of the United States. We may, however, be unable to advance the development of our product candidates in territories outside of the United States, which may limit the market potential for this product candidate.

In situations where we enter into a development and commercial collaborative arrangement for a product candidate, we may also seek to establish additional collaborations for development and commercialization in territories outside of those addressed by the first collaborative arrangement for such product candidate. There are a limited number of potential partners, and we expect to face competition in seeking appropriate partners. If we are unable to enter into any development and commercial collaborations and/or sales and marketing arrangements on acceptable terms, if at all, we may be unable to successfully develop and seek regulatory approval for our product candidates and/or effectively market and sell future approved products, if any, in all of the territories outside of the United States where it may otherwise be valuable to do so.

We may not be successful in maintaining development and commercialization collaborations, and any partner may not devote sufficient resources to the development or commercialization of our product candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop certain of our product candidates and our financial condition and operating results.

Even if we are able to establish collaborative arrangements, any such collaboration may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and prospects. If we partner with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. It is possible that a partner may not devote sufficient resources to the development or commercialization of our product candidate or may otherwise fail in development or commercialization efforts, in which event the development and commercialization of such product candidate could be delayed or terminated and our business could be substantially harmed. In addition, the terms of any collaboration or other arrangement that we establish may not prove to be favorable to us or may not be perceived as favorable, which may negatively impact the trading price of our common

stock. In some cases, we may be responsible for continuing development of a product candidate or research program under a collaboration, and the payment we receive from our partner may be insufficient to cover the cost of this development. Moreover, collaborations and sales and marketing arrangements are complex and time consuming to negotiate, document and implement, and they may require substantial resources to maintain.

We are subject to a number of additional risks associated with our dependence on collaborations with third parties, the occurrence of which could cause our collaborative arrangements to fail, including that:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to issue equity securities that would dilute our stockholders' percentage of ownership;
- we may be required to assume substantial actual or contingent liabilities;
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates;
- business combinations or significant changes in a strategic collaborator's business strategy may affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement; and
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

Additionally, conflicts may arise between us and our partners, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. For example, we are largely dependent on Indivior, which holds the global commercialization rights to our approved product, Suboxone. If any such conflicts were to arise with Indivior or any other partner, such partner could act in its own self-interest, which may be adverse to our interests. Any such disagreement between us and a partner could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates and harm our business:

- reductions in the payment of royalties or other payments we believe are due pursuant to the applicable collaborative arrangement;
- actions taken by a partner inside or outside our collaboration which could negatively impact our rights or benefits under our collaboration; and
- unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities.

Risks Related to Our Business Operations and Industry

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our executive team listed under "Management" located elsewhere in this prospectus, the loss of whose services may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are "at will" employees. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit key executives or the loss of the services of any executive or key employee might impede the progress of our development and commercialization objectives.

Under applicable employment laws, we may not be able to enforce covenants not to compete.

Certain of our executive officers' employment agreements include covenants not to compete. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. We may be unable to enforce these agreements or may not be able to enforce these agreements to their full extent under applicable law. If we cannot demonstrate that such an interest will be harmed, we may be unable to prevent our competitors from benefiting from the expertise of our former employees and our competitiveness may be diminished.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

Our company has been rapidly growing and we expect to continue to grow over the next several years. As our company matures, we expect to expand our employee base to increase our managerial, scientific and engineering, operational, sales, marketing, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our products, if approved, may give rise to potential product liability, and, if successful claims are brought against us, we may incur substantial liability.

As a specialty pharmaceutical company, we operate in a market that is subject to risk of liability. To our knowledge, we are not currently subject to any product liability suits. However, the sales of our approved products and for any product candidates for which we obtain marketing approval and the use of our product candidates in clinical trials (if any), exposes us to the risk of product liability claims alleging adverse effects from such products or product candidates. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates. Any liability claims could have a material adverse effect on our business, financial position, results of operations and future growth prospects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical study participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We may not be able to maintain insurance coverage, and our existing or any future insurance policies or our own resources will not sufficiently cover claims for damages that we may receive in the future.

Our business exposes us to potential product liability and other liability risks that are inherent in clinical development, manufacturing, marketing and use of human therapeutic products. It is generally necessary for us to secure certain levels of insurance as a condition for the conduct of clinical trials and any sale or use of our products. We have taken out product liability insurance with respect to all clinical trials and ongoing trials performed to date for which we were responsible (*i.e.,* in respect of our internal product pipeline). Further, we may seek to expand our insurance coverage if we obtain marketing approval for any of our internal product candidates or if other risks related to our business increase.

Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at an acceptable cost to us or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our product development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of product development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed.

Business interruptions could delay us in the process of developing our product candidates.

Our headquarters are located in Warren, New Jersey and we have manufacturing facilities in Portage, Indiana. If we encounter any disruptions to our operations at these sites or one were to shut down for any reason, including by fire, natural disaster, such as a hurricane, tornado or severe storm, power outage, systems failure, labor dispute or other unforeseen disruption, then we may be prevented from effectively operating our business. Our coverage for natural disasters may be somewhat limited for floods or earthquakes and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include failure to:

- comply with FDA regulations or the regulations applicable in other jurisdictions;
- provide accurate information to the FDA and other regulatory authorities;
- comply with healthcare fraud and abuse laws and regulations in the United States and abroad;
- report financial information or data accurately; or
- disclose unauthorized activities to us.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

Our operations involve hazardous materials and we and third parties with whom we contract must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

As a specialty pharmaceutical company, we are subject to environmental and safety laws and regulations, including those governing the use of hazardous materials. The cost of compliance with health and safety regulations is substantial. Our business activities involve the controlled use of hazardous materials. Our research and development activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and manufacturers and suppliers with whom we may contract are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of accidental contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. We cannot guarantee that that the safety procedures utilized by third-party manufacturers and suppliers with whom we may contract will comply with the standards prescribed by laws and regulations or will eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and U.S. federal and state or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage. In the event of an accident or environmental discharge, we may be held liable for any consequential damage and any resulting claims for damages, which may exceed our financial resources and may materially adversely affect our business, results of operations and prospects, and the value of our shares.

Risks Related to Government Regulation

Changes in law, including as a result of recent presidential administration changes, could have a negative impact on the approval of our product candidates.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 23, 2017, President Trump ordered a hiring freeze for all executive departments and agencies, including the FDA, which prohibited the FDA from filling employee vacancies or creating new positions. While freeze has since been lifted, any additional freezes could result in delays in FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Further and more recently, President Trump has suggested that he plans to seek repeal of all or portions of the PPACA, and he has indicated that he wants Congress to replace the PPACA with new legislation. Risks related to the ongoing efforts of the Trump administration with respect to the repeal or repeal and replacement of elements of the PPACA are described above under the heading "Recently enacted and future healthcare reform legislation or regulation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and may adversely affect the prices we, or they, may obtain and may have a negative impact on our business and results of operations." We cannot predict whether other legislative changes will be adopted, if any, or how such changes would affect the pharmaceutical industry generally.

If the FDA does not conclude that our product candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product candidates under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for each of our product candidates described in this prospectus. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug, and Cosmetic Act, or FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant.

If the FDA does not allow us to pursue the 505(b)(2) regulatory pathway for our product candidates as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact

our competitive position and prospects. Even if we are allowed to pursue the 505(b)(2) regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain competitors and others have objected to the FDA's interpretation of Section 505(b)(2). We expect that our competitors will file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical studies that support their approval, contain deficiencies. If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its Section 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development.

Clinical testing, even when utilizing the 505(b)(2) pathway, is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, even with active ingredients that have previously been approved by the FDA as safe and effective. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

Our product candidates are in various stages of development, from early stage to late stage. Clinical trial failures may occur at any stage and may result from a multitude of factors both within and outside our control, including flaws in formulation, adverse safety or efficacy profile and flaws in trial design, among others. If the trials result in negative or inconclusive results, we or our collaborators may decide, or regulators may require us, to discontinue trials of the product candidates or conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. For these reasons, our future clinical trials may not be successful.

We do not know whether any future clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If any product candidate for which we are conducting clinical trials is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it. If we are unable to bring any of our current or future product candidates to market, our business would be materially harmed and our ability to create long-term stockholder value will be limited.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and could jeopardize or delay our ability to obtain regulatory approval and commence product sales. We may also find it difficult to enroll patients in our clinical trials, which could delay or prevent development of our product candidates.

We may experience delays in clinical trials of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including:

- inability to raise or delays in raising funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, or failure by such CROs to carry out the clinical trial at each site in accordance with the terms of our agreements with them;

- delays in obtaining required institutional review board, or IRB, approval at each site;
- difficulties or delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites electing to terminate their participation in one of our clinical trials, which would likely have a detrimental effect on subject enrollment; or
- time required to add new clinical sites.

If initiation or completion of our planned clinical trials is delayed for any of the above reasons or other reasons, our development costs may increase, our regulatory approval process could be delayed and our ability to commercialize and commence sales of our product candidates could be materially harmed, all of which could have a material adverse effect on our business.

In addition, identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates as well as completion of required follow-up periods. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics or to complete our clinical trials in a timely manner. Patient enrollment is and completion of the trials is affected by factors including:

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under trial;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

Our products or product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance, or result in significant negative consequences following marketing approval, if any.

As with many pharmaceutical and biological products, treatment with our products or product candidates may produce undesirable side effects or adverse reactions or events. Although the nature of our products or product candidates as containing active ingredients that have already been approved means that the side effects arising from the use of the active ingredient or class of drug in our products or product candidates is generally known, our products or product candidates may still cause undesirable side effects. These could be attributed to the active ingredient or class of drug or to our unique formulation of such products or product candidates, or other potentially harmful characteristics. Such characteristics could cause us, our IRBs, clinical trial sites, the FDA or other regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay, denial or withdrawal of regulatory approval, which may harm our business, financial condition and prospects significantly.

Further, if any of our products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution;
- the FDA may require implementation of a Risk Evaluation and Mitigation Strategy, or REMS;

- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or product candidate and could substantially increase the costs of commercializing our products and product candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date we have obtained regulatory approval for two products in the United States, but it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval in the United States or other jurisdictions.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree that our changes to branded reference drugs meet the criteria for the 505(b)(2) regulatory pathway or foreign regulatory pathways;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective or comparable to its branded reference product for its proposed indication;
- the results of any clinical trials we conduct may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- we or third-party API or component manufacturers with which we may contract may be unable to maintain a compliance status acceptable to the FDA or comparable foreign regulatory authorities or the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes identified in our marketing application; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would harm our business, results of operations and prospects significantly.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates.

We have limited experience using the 505(b)(2) regulatory pathway to submit an NDA or any similar drug approval filing to the FDA, and we cannot be certain that any of our product candidates will receive regulatory approval. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If we are found to have improperly promoted off-label uses of our products or product candidates, if approved, we may become subject to significant liability. Such enforcement has become more common in the industry. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for our product candidates for our proposed indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment it could be used in such manner. However, if we are found to have promoted our products for any off-label uses, the federal government could levy civil, criminal and/or administrative penalties, and seek fines against us. The FDA or other regulatory authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Our business is subject to extensive regulatory requirements and our approved product and product candidates that obtain regulatory approval will be subject to ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize such products.

Even after a product is approved, we will remain subject to ongoing FDA and other regulatory requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, import, export, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report adverse events, or AEs, and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. In addition, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. For example, a product's approval may contain requirements for potentially costly post-approval studies and surveillance to monitor the safety and efficacy of the product, or the imposition of a REMS program.

The holder of an NDA is subject to payment of user fees and adherence to commitments made in the NDA. A manufacturer is also subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs. If we or a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing.

If we or our products or product candidates or our manufacturing facilities fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters asserting that we are in violation of the law;
- impose restrictions on the marketing or manufacturing of the product;
- seek an injunction or impose civil, criminal and/or administrative penalties, damages, assess monetary fines, require disgorgement, consider exclusion from participation in Medicare, Medicaid and other federal healthcare programs and require curtailment or restructuring of our operations;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize product; or
- refuse to allow us to enter into government contracts.

Similar post-market requirements may apply in foreign jurisdictions in which we may seek approval of our products. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenues.

In addition, the FDA's regulations, policies or guidance may change and new or additional statutes or government regulations in the United States and other jurisdictions may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products and/or product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

We are required to obtain regulatory approval for each of our products in each jurisdiction in which we intend to market such products, and the inability to obtain such approvals would limit our ability to realize their full market potential.

In order to market products outside of the United States, we must comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. However, the failure to obtain regulatory approval in one jurisdiction may adversely impact our ability to obtain regulatory approval in another jurisdiction. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

If we fail to develop, acquire or in-license other product candidates or products, our business and prospects will be limited.

Our long-term growth strategy is to develop and commercialize a portfolio of product candidates in addition to our existing product candidates. We may also acquire or in-license early to mid-stage new chemical entities, or NCEs. Although we have internal research and development capacity that we believe will enable us to make improvements to existing compounds or active ingredients, we do not have internal

drug discovery capabilities to identify and develop entirely new chemical entities or compounds. As a result, our primary means of expanding our pipeline of product candidates is to develop improved formulations and administration methods for existing FDA-approved products and/or select and acquire or in-license product candidates for the treatment of therapeutic indications that complement or augment our current targets, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Developing new formulations of existing products or identifying, selecting and acquiring or in-licensing promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual development, acquisition or in-license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to add additional product candidates to our pipeline, our long-term business and prospects will be limited.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and our product candidates. The issuance, scope, validity, enforceability, strength and commercial value of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover the products, if approved, or product candidates in the United States or in foreign countries or territories. If this were to occur, early generic competition could be expected against our products, if approved, and our product candidates in development. There may be relevant prior art relating to our patents and patent applications which could invalidate a patent or prevent a patent from issuing based on a pending patent application. In particular, because the active pharmaceutical ingredients in many of our product candidates have been on the market as separate products for many years, it is possible that these products have previously been used off-label in such a manner that such prior usage would affect the validity of our patents or our ability to obtain patents based on our patent applications.

The patent prosecution process is expensive and time-consuming. We or our licensors may not be able to prepare, file and prosecute all necessary or desirable patent applications for a commercially reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we or our licensors may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, depending on the terms of any future in-licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development and reformulation processes that involve proprietary know-how, information or technology that is not covered by patents. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and

proprietary information. For example, the FDA is considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our products, if approved, or product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement rights are not as strong as that in the United States or Europe. These products may compete with our products or product candidates, and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before grant. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or USPTO, has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that still require the USPTO to issue new regulations for their implementation and it may take the courts years to interpret the provisions of the new statute.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce existing patents or patents that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce existing patents or patents that we may obtain in the future. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of any potential licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the

technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

As described in the section titled “Business — Legal Proceedings,” several of our issued patents are involved in litigations. In addition to the challenges we face in those litigations, a number of our issued patents are or have been involved in administrative proceedings, such as reexamination and *inter partes* review at the USPTO and opposition at the EPO. We cannot be certain that all claims of the challenged patents will be upheld or that the challenged patents will be found infringed. We may lose any of the challenged patents entirely, or we may have to amend the scope of claims to the extent which may be considered insufficient to cover our products or product candidates. If any of those scenarios were to occur, we might lose our competitive advantage in our market, and our business could be materially affected.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. For more information, please see the subsection “Patent-Related Litigation” under the section titled “Business – Legal Proceedings.”

***The patents and patent applications that we have covering our products and product candidates are limited to specific formulations and manufacturing processes, and our market opportunity for our products and product candidates may be limited by the lack of patent protection for the active ingredients and by competition from other formulations and manufacturing processes, as well as administration methods that may be developed by competitors*.**

We have obtained, and continue to seek to obtain patent protection for our manufacturing technology, drug administering technology and our products and product candidates, including specific formulations and manufacturing processes, which may not be as effective as composition of matter coverage in preventing work-arounds by competitors. As a result, generic products that do not infringe the claims of our issued patents covering formulations and processes are, or may be, available while we are marketing our products. Competitors who obtain the requisite regulatory approval will be able to commercialize products with the same active ingredients as our products or product candidates so long as the competitors do not infringe any process, use or formulation patents that we have developed for our products or product candidates, subject to any regulatory exclusivity we may be able to obtain for our products.

The number of patents and patent applications covering products containing the same active ingredient as our products or product candidates indicates that competitors have sought to develop and may seek to commercialize competing formulations that may not be covered by our patents and patent applications. The commercial opportunity for our products or product candidates could be significantly harmed if competitors are able to develop and commercialize alternative formulations of our products or product candidates that are different from ours and do not infringe our issued patents covering our products or use of our products.

Suboxone and Zuplenz have been approved by the FDA, and we anticipate that other product candidates will be approved by the FDA in the future. As additional products of ours are on the market, one or more third parties may also challenge the patents that we control covering our products, which could result in the invalidation or unenforceability of some or all of the relevant patent claims of our issued patents covering our products.

Suboxone and Zuplenz have been approved by the FDA, and we anticipate that other product candidates will be approved by the FDA in the future. Once our products are on the market, one or more third parties may challenge the patents that we control covering our products in court or the USPTO, which could result in the invalidation or unenforceability of some or all of the relevant patent claims of our issued patents covering our products.

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering one of our products or product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (*e.g.,* opposition proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and licensed patents and/or applications and any patent rights we may own or license in the future. We rely on our outside counsel or our licensing partners to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patents or patent applications, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

Our drug development strategy relies heavily upon the 505(b)(2) regulatory pathway, which requires us to certify that we do not infringe upon third-party patents covering approved drugs. Such certifications typically result in third-party claims of intellectual property infringement, the defense of which will be costly and time consuming, and an unfavorable outcome in any litigation may prevent or delay our development and commercialization efforts which would harm our business.

Litigation or other proceedings to enforce or defend intellectual property rights are often complex in nature, may be very expensive and time-consuming, may divert our management's attention from other aspects of our business and may result in unfavorable outcomes that could adversely impact our ability to launch and market our product candidates, or to prevent third parties from competing with our products and product candidates.

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the USPTO. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

In particular, our commercial success depends in large part on our avoiding infringement of the patents and proprietary rights of third parties for existing approved drug products. Because we utilize the 505(b)(2) regulatory pathway for the approval of our products and product candidates, we rely in whole or in part on studies conducted by third parties related to those approved drug products. As a result, upon filing with the FDA for approval of our product candidates, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our proposed drug product. When we submit a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to the patent owner once our 505(b)(2) NDA is accepted for filing by the FDA. The third party may then initiate a lawsuit against us to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our NDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in our favor. If the third party does not file a patent infringement lawsuit within the required 45-day period, our NDA will not be subject to the 30-month stay.

In addition to paragraph IV litigation noted above, third-party owners of patents may generally assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations or methods of manufacture related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending or subsequently filed patent applications which may later result in issued patents that may be infringed by our products or product candidates. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our product candidates, including the formulation, any method or process involved in the manufacture of any of our product candidates, any molecules or intermediates formed during such manufacturing process or any other attribute of the final product itself, the holders of any such patents may be able to block our ability to commercialize our product candidates unless we obtain a license under the applicable patents, or until such patents expire. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may request and/or obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates on a temporary or permanent basis. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products or manufacturing processes, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research, manufacture clinical trial supplies or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our products or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates and companion diagnostic. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to our products or product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or any potential future licensors or might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable as a result of legal challenges by our competitors;
- issued patents that we own or have exclusively licensed may not provide coverage for all aspects of our products or product candidates in all countries;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to this Offering and Ownership of Our Common Stock

No public market for our common stock currently exists, and a public market may not develop or be liquid enough for you to sell your shares quickly or at market price.

Prior to this offering, there has not been a public market for our common stock. If an active trading market for our common stock does not develop following this offering, you may not be able to sell your shares quickly or at the market price. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares of our common stock and may impair our ability to acquire other companies or technologies by using our common stock as consideration. The initial public offering price of our common stock will be determined by negotiations between us and representatives of the underwriters, and may not be indicative of the market prices of our common stock that will prevail in the trading market.

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

The market price of our common stock is likely to be volatile. The stock market in general and the market for biopharmaceutical or pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including:

- sales of our approved products;
- results of clinical trials of our current and any future product candidates or those of our competitors;
- the success of competitive drugs or therapies;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our current and any future product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- our inability to obtain or delays in obtaining adequate drug supply for any approved drug or inability to do so at acceptable prices;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

Our quarterly operating results may fluctuate significantly, and these fluctuations could cause our stock price to decline.

We expect our operating results to be subject to quarterly, and possibly annual fluctuations. These fluctuations could cause our stock price to decline. Our net loss and other operating results will be affected by numerous factors, including:

- whether the FDA requires us to complete additional, unanticipated studies, trials or other activities prior to approving any of our current and future product candidates, which would likely delay any such approval;
- our execution of other collaborative, licensing or similar arrangements and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our future development programs;
- any product liability or intellectual property infringement lawsuit in which we may become involved;
- regulatory developments any of our other current and future product candidates, or the product candidates of our competitors; and
- if any of our current or future product candidates receive regulatory approval, the level of underlying demand for such product candidate and wholesaler buying patterns.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of , our executive officers, directors, 5% or greater stockholders and their affiliates beneficially own approximately % of our voting stock. Based upon the assumed number of shares to be sold in this offering as set forth on the cover page of this prospectus, upon the closing of this offering, that same group will beneficially own approximately % of our outstanding voting stock. Bratton Capital Management L.P., which controls certain of our major stockholders, has beneficial ownership of approximately % of our common stock as of . Therefore, even after this offering these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely, in part, on the research and reports that industry or financial analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by industry or financial analysts. If no, or few, analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

We may incur substantial costs relating to "excess parachute payments" under Sections 280G and 4999 of the Internal Revenue Code of 1986, as amended.

We entered into employment agreements with Keith J. Kendall, our Chief Executive Officer, and A. Mark Schobel, our Chief Innovation and Technology Officer, pursuant to which they are each entitled to receive an additional tax indemnification payment, or a "gross-up" payment, if the payments and benefits

under their respective employment agreements or any other benefits plans and programs trigger excise tax liability under Sections 280G and 4999 of the Internal Revenue Code of 1986, as amended, or the Code for "excess parachute payments." Under Sections 280G and 4999 of the Code, the excise tax is triggered by change in control-related payments that equal or exceed three times Mr. Kendall's or Mr. Schobel's, as applicable, average annual taxable compensation over the five calendar years preceding the change in control. The excise tax equals 20% of the amount of the payment in excess of one times Mr. Kendall's or Mr. Schobel's, as applicable, average taxable compensation over the preceding five calendar year period (*i.e.,* the excess parachute payments). We may not take a federal tax deduction for Mr. Kendall's and/or Mr. Schobel's excess parachute payments.

If an "excess parachute payment" is made to Mr. Kendall and/or Mr. Schobel, we would incur substantial costs related to a change in control of the Company due to the gross-up payment and the lost federal tax deduction for Mr. Kendall's and/or Mr. Schobel's excess parachute payments.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last day business day of our most recently completed second fiscal quarter, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. As an emerging growth company, we have elected to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public emerging growth companies.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over

financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and Nasdaq have imposed various requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that required the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the pro forma as adjusted book value (deficit) per share of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of $ per share, based on an assumed initial public offering price of $ per share (the mid-point of the price range set forth on the cover page of this prospectus) and our pro forma as adjusted net tangible book value (deficit) as of December 31, 2017. For more information on the dilution you may suffer as a result of investing in this offering, see "Dilution."

This dilution is due to the substantially lower price paid by our investors who purchased shares prior to this offering as compared to the price offered to the public in this offering and the exercise of stock options potentially granted to our employees. The exercise of any of these options if granted would result in additional dilution. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.

Sales of a substantial number of shares of our common stock by our existing stockholders, including shares issued to employees and directors in respect of the intended termination of our Performance Unit Plans, or PUP Plans, in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock.

Substantially all of our existing stockholders are subject to lock-up agreements with the underwriters of this offering that restrict the stockholders' ability to transfer shares of our common stock for at least 180 days after the date of this prospectus. The lock-up agreements limit the number of shares of common stock that may be sold immediately following the public offering. Subject to certain limitations, including sales volume limitations with respect to shares held by our affiliates, substantially all of our outstanding shares prior to this offering will become eligible for sale upon expiration of the lock-up period, as

calculated and described in more detail in the section of this prospectus entitled “Shares Eligible for Future Sale.” In addition, shares issued or issuable upon exercise of options and warrants vested as of the expiration of the lock-up period will be eligible for sale at that time. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up arrangement described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future issuances of our common stock or rights to purchase our common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

While we currently do not have any options outstanding, we intend to adopt a new equity incentive plan and, following consummation of this offering, we intend to grant options to purchase shares of our common stock or other forms of equity compensation to our employees and directors. We intend to register all shares of common stock that we may issue under our stock-based compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to any applicable lock-up agreements and the restrictions imposed under Rule 144 under the Securities Act, which may cause our stockholders to experience additional dilution.

If Perceptive chooses to exercise certain warrants, it may result in immediate and substantial dilution to our existing stockholders.

In connection with the entry into the Loan Agreement, Perceptive received warrants, or the Perceptive Warrants. The Perceptive Warrants expire on August 16, 2023 and are subject to anti-dilution adjustments so that, upon exercise, they will represent 4.5% of our fully diluted common stock on an as converted basis. If Perceptive chooses to exercise such warrants and the underlying shares of common stock are issued upon such exercise are sold, our stockholders may experience immediate and substantial dilution and the market price of our shares of common stock could decline. Further, the perception that such securities might be exercised could adversely affect the trading price of our shares of common stock. In addition, during the time that such securities are outstanding, they may adversely affect the terms on which we could obtain additional capital.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in the section of this prospectus entitled “Use of Proceeds,” and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses since inception and do not expect to become profitable in the near future, if ever. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Section 382 of the Code, if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. We believe that, with our initial public offering, we may have triggered an “ownership change” limitation. In addition, we may experience ownership changes

in the future as a result of subsequent shifts in our stock ownership, including an ownership change as a result of the combined effect of our initial public offering and future equity offerings. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of “blank check” preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a classified board of directors;
- establishing a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation, or certificate of incorporation, or our amended and restated bylaws, or bylaws;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Our bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our bylaws provide that, subject to limited exceptions, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, any action asserting a claim against us arising pursuant to any

provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws or any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. The forward-looking statements are contained principally in the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business.” These forward-looking statements involve a number of risks and uncertainties. We caution readers that any forward-looking statement is not a guarantee of future performance and that actual results could differ materially from those contained in the forward-looking statement. These statements are based on current expectations of future events. Such statements include, but are not limited to, statements about future financial and operating results, plans, objectives, expectations and intentions, costs and expenses, interest rates, outcome of contingencies, financial condition, results of operations, liquidity, cost savings, objectives of management, business strategies, success of competing drugs, financing, potential growth and market opportunities, product pipeline, clinical trial timing and plans, clinical and regulatory pathways for our development programs, the achievement of clinical and commercial milestones, the advancement of our technologies and our proprietary, co-developed and partnered products and product candidates, and other statements that are not historical facts. In some cases, you can identify these statements by terms such as “anticipate,” “believe,” “could,” “estimate,” “expects,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms, and similar expressions. We intend that such forward-looking statements be subject to the safe harbors created thereby.

These forward-looking statements are based on the current beliefs and expectations of our management with respect to future events and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results may differ materially from current expectations and projections. We discuss many of these risks in greater detail under the heading “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date made.

All subsequent written or oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We do not undertake any obligation to release publicly any revisions to these forward-looking statements to reflect events or circumstances after the date of this prospectus supplement or to reflect the occurrence of unanticipated events, except as may be required under applicable United States securities law. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

MARKET AND INDUSTRY DATA

Certain market and industry data included in this prospectus were obtained from independent third-party surveys, market research, publicly available information, reports of governmental agencies and industry publications and surveys. All of the market and industry data used in this prospectus involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Although we are responsible for all of the disclosure contained in this prospectus and we believe the information from the industry publication and other third-party sources included in this prospectus is reliable, such information is inherently imprecise. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $ million (or approximately $ million if the underwriters' option to purchase additional shares is exercised in full) from the sale of the shares of common stock offered by us in this offering, based on an assumed initial public offering price of $ per share (the mid-point of the price range set forth on the cover page of this prospectus), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share (the mid-point of the price range set forth on the cover of this prospectus) would increase (decrease) the net proceeds to us from this offering by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase (decrease) of shares in the number of shares offered by us, as set forth on the cover of this prospectus, would increase (decrease) the net proceeds to us by $ million, assuming the assumed initial public offering price of $ per share (the mid-point of the price range set forth on the cover of this prospectus) remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public equity markets. We intend to use the net proceeds of this offering, together with our existing cash and cash equivalents and cash generated from existing partnerships, as follows:

- approximately $ million to fund pre-launch commercialization investments for our late-stage epilepsy products, Libervant and Sympazan, as well as our ALS product candidate, AQST-117;
- approximately $ million to fund the commencement of our clinical trials for our complex molecules AQST-108 and AQST-305;
- approximately $ million to identify our new pipeline candidates in CNS diseases and other therapeutic categories and indications; and
- the remainder for general corporate purposes, including working capital and capital expenditures.

We believe that the net proceeds from this offering, combined with the revenue from partnered product activities and our existing cash and cash equivalents, will be sufficient to fund our operations at least through the next 24 months, including the investments identified above. Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the consummation of this offering, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including our ability to obtain additional financing, the progress, cost and results of our proprietary commercialized product candidate programs, including our planned clinical trials, and whether we are able to enter into future collaborative arrangements. As a result, our management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds from this offering.

Pending their use, we plan to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the United States government.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of December 31, 2017:

- on an actual basis;
- on a pro forma basis to give effect to: (i) conversion of redeemable Preferred A-3 and A-2 interests and accrued dividends at a rate of 8% and 6%, respectively; (ii) granting of additional PUPs to maintain 5% ownership converted to shares of common stock and valuation and conversion thereof; and (iii) conversion of PUPs and valuation thereof to shares of common stock; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of shares of our common stock offered in the offering, assuming an initial public offering price of $ per share (the mid-point of the price range set forth on the cover of this prospectus), after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information below is illustrative only and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with our audited consolidated financial statements and the related notes appearing elsewhere in this prospectus, the sections entitled “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and other financial information contained in this prospectus.

	As of December 31, 2017		
(In thousands, except share and per share data)	Actual	Pro Forma	Pro Forma As Adjusted[1]
		(unaudited)	
Cash and cash equivalents	$ 17,379	$	$
Long-term debt	45,507		
Redeemable preferred A-3 interests and accrued dividends	5,896	—	—
Redeemable preferred A-2 interests and accrued dividends	36,205	—	—
Members’ / Stockholders’ equity:			
Preferred A interests, no par value. Authorized 100,000,000 units; 16,886,750 units issued and outstanding at December 31, 2017; no units issued and outstanding, pro forma and pro forma as adjusted	16,887	—	—
Preferred A-1 interests, no par value. Authorized 100,000,000 units; 21,526,850 units issued and outstanding at December 31, 2017; no units issued and outstanding, pro forma and pro forma as adjusted	21,883	—	—
Common interests, no par value. Authorized 500,000,000 units; 121,228,353 units issued and outstanding at December 31, 2017; and no units issued and outstanding, pro forma and pro forma as adjusted	12,727	—	—
Common stock, $0.001 par value per share: Authorized no shares; no shares issued and outstanding at December 31, 2017; authorized shares; shares issued and outstanding, pro forma; authorized shares; and shares issued and outstanding, pro forma as adjusted	—	247	
Additional paid-in capital	—	90,871	
Accumulated deficit	(120,093)	(117,613)	—
Total members’ / stockholders’ deficit	(68,596)	(26,495)	
Total capitalization	$ 43,116	$ 43,116	$

(1) A $1.00 increase (decrease) in the assumed initial public offering price of $ per share (the mid-point of the price range set forth on the cover page of this prospectus) would increase (decrease) each of cash, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of shares in the number of shares we are offering would increase (decrease) cash, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by approximately $ million, assuming the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The table above excludes the following:

- shares of common stock issuable upon the exercise of warrants to purchase 4.5% of our common stock on a fully diluted basis through August 16, 2023 at an exercise price of $0.01 per share; and
- shares of common stock reserved for future issuance under the 2018 Plan.

DILUTION

If you invest in our common stock in this offering, your interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock upon consummation of this offering. Dilution results from the fact that the initial public offering price is substantially in excess of the book value per share attributable to the existing stockholders for the presently outstanding stock.

Our historical net tangible book value (deficit) in our common stock as of December 31, 2017 was approximately $(68.9) million, or $(0.57) per share of common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our liabilities and preferred stock which is not included within equity. Net historical tangible book value (deficit) per share is our historical net tangible book value (deficit) divided by the number of shares of common stock outstanding as of December 31, 2017. Our pro forma net tangible book value (deficit) as of December 31, 2017 was approximately $ ____ million, or $____ per share of common stock. Pro forma net tangible book value (deficit) gives effect to the conversion of all of our outstanding preferred units and common units into an aggregate of shares of our common stock, assuming an initial public offering price of $ per share (the mid-point of the range set forth on the cover of this prospectus).

Pro forma as adjusted net tangible book value is our pro forma net tangible book value (deficit), plus the effect of the sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share (the mid-point of the range set forth on the cover of this prospectus), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. This amount represents an immediate increase in pro forma as adjusted net tangible book value of $ per share to our existing stockholders, and an immediate dilution of $ per share to new investors participating in this offering.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		$
Historical net tangible book value (deficit) per share as of December 31, 2017	$(0.57)	
Pro forma decrease in net tangible book value per share as of December 31, 2017, attributable to pro forma transactions and other adjustments described above	—	
Pro forma net tangible book value per share as of December 31, 2017		
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering	—	
Pro forma as adjusted net tangible book value per share after this offering		—
Dilution in net tangible book value per share to new investors participating in this offering		$

The dilution information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. A $1.00 increase (decrease) in the assumed initial public offering price of $ per share (the mid-point of the price range set forth on the cover page of this prospectus) would increase (decrease) the pro forma as adjusted net tangible book value (deficit) per share after this offering by approximately $ per share and the pro forma dilution per share to investors participating in this offering would be approximately $ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. A share increase in the number of shares offered by us, as set forth on the cover of this prospectus, would increase the pro forma as adjusted net tangible book value (deficit) per share after this offering by approximately $ and the pro forma dilution per share to investors participating in this offering would be approximately $, assuming the assumed initial public offering price of $ per share (the mid-point of the price range set forth on the cover of this prospectus) remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, a share decrease in the number of shares offered by us, as set forth on the cover of this prospectus, would decrease the pro forma as adjusted net tangible book value (deficit) per share after this offering by approximately $ and the pro forma

dilution per share to investors participating in this offering would be approximately $, assuming the assumed initial public offering price of $ per share (the mid-point of the price range set forth on the cover of this prospectus) remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option in full to purchase additional shares of our common stock in this offering, the pro forma as adjusted net tangible book value will increase to $ per share, representing an immediate increase to existing stockholders of $ per share and an immediate dilution of $ per share to new investors participating in this offering.

The following table summarizes, as of December 31, 2017, on a pro forma as adjusted basis as described above, the total number of shares of common stock purchased from us on an as converted to common stock basis, the total consideration paid or to be paid, and the average price per share paid or to be paid by existing stockholders and by new investors in this offering at an assumed initial public offering price of $ per share (the mid-point of the price range set forth on the cover page of this prospectus), before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. As the table below shows, investors participating in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares purchased		Total consideration		
	Number	Percent	Amount (in thousands)	Percent	Average price per share
Existing stockholders before this offering		%	$	%	$
Investors participating in this offering					
Total		100%	$	100%	

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share (the mid-point of the price range set forth on the cover page of this prospectus) would increase (decrease) the total consideration paid by investors participating in this offering and total consideration paid by all stockholders by $ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by percentage points, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

Similarly, each share increase (decrease) in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by investors participating in this offering and total consideration paid by all stockholders by $ million, and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by percentage points, assuming the assumed initial public offering price remains the same.

If the underwriters exercise their option to purchase additional shares in full in this offering, the number of shares of common stock held by existing stockholders will be reduced to % of the total number of shares of common stock to be outstanding after this offering, and the number of shares of common stock held by investors participating in this offering will be further increased to , or % of the total number of shares of common stock to be outstanding after this offering.

The foregoing discussion is based on shares of common stock outstanding as of December 31, 2017, assuming an initial public offering price of $ (the mid-point of the range set forth on the cover of this prospectus) and excludes:

- shares of common stock issuable upon the exercise of warrants to purchase 4.5% of our common stock on a fully diluted basis through August 16, 2023 at an exercise price of $0.01 per share; and
- shares of common stock reserved for future issuance under our 2018 Plan.

New investors will experience further dilution if any new options are issued and exercised under our equity incentive plans or we issue additional shares of common stock, other equity securities or convertible debt securities in the future.

SELECTED CONSOLIDATED FINANCIAL DATA

The following selected financial data should be read together with our consolidated financial statements and accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus. The selected financial data in this section is not intended to replace our consolidated financial statements and the accompanying notes and are qualified in their entirety by the consolidated financial statements and the related notes included elsewhere in this prospectus.

The following tables set forth our financial data for and as of the years ended December 31, 2017 and 2016, all of which has been derived from our audited consolidated financial statements appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected for any period in the future.

	Year Ended December 31,	
	2017	2016
(In thousands, except per membership interest and per share data)		
Statements of Operations Data:		
Revenues	$ 66,918	$ 51,785
Costs and expenses:		
Manufacture and supply	19,820	16,378
Research and development	22,133	15,450
Selling, general and administrative	25,078	20,804
Total costs and expenses	67,031	52,632
Operating loss	(113)	(847)
Other expenses:		
Interest expense	(7,707)	(6,143)
Loss on extinguishment of debt	—	(757)
Loss on impairment of investment	—	(1,006)
Change in fair value of warrant	(1,123)	(750)
Other income (expense)	—	(99)
Net loss before income taxes	(8,943)	(9,602)
Income taxes	—	—
Net loss	(8,943)	(9,602)
Dividends on redeemable preferred interests	(2,480)	(2,342)
Net loss attributable to members' interests	(11,423)	(11,944)
Comprehensive loss	$ (11,423)	$ (11,944)
Net loss per membership interest	$ (0.09)	$ (0.10)
Weighted-average number of membership interests outstanding used to compute net loss per share membership interests	121,228,353	118,785,104
Unaudited pro forma net loss(1)	$ (8,943)	
Unaudited pro forma net loss per share of common stock(1)	$ (0.04)	
Unaudited pro forma weighted-average number of shares of common stock outstanding used to compute net loss per share of common stock(1)	246,768,153	

(1) See Note 2 of our notes to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the pro forma net loss, net loss per share and the weighted-average number of shares used in the computation of the per share amounts.

	December 31, 2017	December 31, 2016
(In thousands)		
Balance Sheet Data:		
Cash and cash equivalents	$ 17,379	$ 9,209
Working capital(1)	12,813	12,526
Total assets	43,116	39,389
Total debt	45,507	38,650
Accumulated deficit	(120,093)	(108,670)
Members' deficit	(68,596)	(57,197)

(1) Working capital is defined as current assets less current liabilities. See our consolidated financial statements for additional information regarding our current assets and current liabilities.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing at the end of this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a specialty pharmaceutical company focused on identifying, developing and commercializing differentiated products to address unmet medical needs. We have a late-stage proprietary product pipeline focused on the treatment of CNS diseases. We believe that the characteristics of these patient populations and shortcomings of available treatment options create opportunities for the development and commercialization of meaningfully differentiated medicines. Our most advanced proprietary product candidates, which we intend to commercialize ourselves, include (i) Libervant, a buccal soluble film formulation of diazepam for the treatment of recurrent epileptic seizures, for which we expect to submit an NDA in 2018; (ii) Sympazan, an oral soluble film formulation of clobazam for the treatment of seizures associated with a rare, intractable form of epilepsy known as LGS, for which we submitted an NDA in October 2017 and have been given an August 31, 2018 PDUFA date, and (iii) AQST-117, an oral soluble film formulation of riluzole for the treatment of Amyotrophic Lateral Sclerosis, or ALS, for which we expect to submit an NDA in 2018. We have also developed a proprietary pipeline of complex molecule-based products addressing large market opportunities beyond CNS indications, which include (i) AQST-108, a sublingual film formulation of epinephrine for the treatment of anaphylaxis, for which we expect to begin additional Phase 1 trials in 2018 and (ii) AQST-305, a buccal film formulation of octreotide for the treatment of acromegaly and neuroendocrine tumors, for which we expect to begin human proof of concept trials in 2018.

In addition to these product candidates, we have a portfolio of commercialized and development-stage partnered products. These products include Suboxone, a sublingual film formulation of buprenorphine and naloxone, which is the market leader for the treatment of opioid dependence. We manufacture all of our partnered and proprietary products at our FDA- and DEA-inspected facilities and anticipate that our current manufacturing capacity is sufficient for commercial quantities of our products and product candidates currently in development. We have produced over 1.1 billion doses of Suboxone in the last four years and over three billion commercial doses or dose equivalents for all customers since 2008. Our products are developed using our proprietary PharmFilm technology and know-how. Our patent portfolio currently comprises at least 200 issued patents worldwide, of which at least 40 are U.S. patents, and more than 75 pending patent applications worldwide.

We were originally formed in Delaware in January 2004 as MonoSol Rx, LLC. We converted from a Delaware limited liability company to a Delaware corporation and changed our name to Aquestive Therapeutics, Inc. on January 1, 2018. We generated $66.9 million and $51.8 million of revenue in 2017 and 2016, respectively, largely from commercial products marketed by our partners that generated manufacturing and supply revenues, and licensing, royalty and co-development and research fees. Suboxone, which was launched in 2010, was our first partnered pharmaceutical product to be commercialized, and we have multiple other partner relationships that contribute significantly to our revenue and future revenue opportunities from partnered products.

In 2013, we made a strategic decision to develop our own pipeline of proprietary pharmaceutical products and to pursue commercialization of these products. We expect revenues from these development efforts to start being realized in 2019, subject to applicable regulatory approval. Substantial investments have been made since 2013 in the development of our proprietary pipeline. We expect to continue these investments and invest in pre-launch commercialization initiatives throughout 2018 and 2019 in advance of the planned commercial launches of our CNS products. A portion of these development and commercialization investments has been funded by partner-related revenues, which we

expect to continue. In addition, we have funded our activities with a $50.0 million senior credit facility with Perceptive, or the Loan Agreement (see Liquidity and Capital Resources), and equity investments, most of which were made prior to 2009.

As of December 31, 2017, we had $17.4 million in cash and cash equivalents. As a result of our investments in product development and recent investments in pre-launch commercialization initiatives, as of December 31, 2017, we had an accumulated deficit of $120.1 million. We recorded net losses of $8.9 million and $9.6 million for the years ended December 31, 2017 and 2016, respectively.

We expect to continue to incur net losses for the next few years as we pursue the development and commercialization of our proprietary product candidates. Our net losses may fluctuate significantly from period to period, depending on the timing of our planned clinical trials and expenditures on our other research and development and commercial development activities. We expect our expenses will increase substantially over time as we:

- fund commercialization investments for our epilepsy products, Libervant and Sympazan, and our ALS product, AQST-117;
- continue clinical development of our complex molecules, AQST-108 and AQST-305;
- identify new pipeline candidates in CNS diseases and other indications; and
- are faced with increased working capital requirements and possible capital expenditures.

Our business has been financed through a combination of revenue from partnered product activities, equity investments from our stockholders and debt proceeds from our credit facilities. In addition to proceeds from this offering, we may require additional financing to execute our business strategy.

We believe that the net proceeds from this offering, combined with our existing cash and cash equivalents and expected revenue from our partnered product activities, will be sufficient to fund our operations at least through the next 24 months of operations, including our planned investments in the pre-launch commercialization of our late stage CNS product candidates, research and development investments in our complex molecule product pipeline candidates, capital expenditures and investments in new product candidates in epilepsy and other CNS diseases. We have based this estimate on assumptions that could change, and we could utilize our available financial resources sooner than we currently expect. The key assumptions underlying this estimate include:

- the costs necessary to successfully complete our development efforts of our proprietary product candidates;
- continued revenue from our partnered products at levels similar to or above recent years' results;
- the levels and timing of revenues and costs of commercialization of our late stage CNS product candidates; and
- the infrastructure costs to support a public company.

We have no committed sources of additional capital. We may attempt to raise additional capital due to favorable market conditions or other strategic considerations even if we have sufficient funds for planned operations. Until we become profitable, if ever, we may need to raise additional capital in the future to further the development and commercialization of our epilepsy products, Libervant and Sympazan, our ALS product, AQST-117, and our other product candidates. We may seek to obtain additional financing in the future through the issuance of our common stock, through other public or private equity or debt financings, through collaborations or partnerships with other companies or other means, if available. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan and cause us to delay or curtail our operations until such funding is received. To the extent that we raise additional funds by issuance of equity securities, our stockholders may experience dilution, and debt financings, if available, may involve restrictive covenants or may otherwise constrain our financial flexibility. To the extent that we raise additional funds through collaborative arrangements, it may be

necessary to relinquish some rights to our intellectual property or grant licenses on terms that are not favorable to us. In addition, payments made by potential collaborators or licensors generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones may harm our future capital position.

Financial Operations Overview

Revenues

Our revenues to date have been earned from partnered pipeline and marketed product activities. These activities generate revenues in three primary categories: co-development and research fees, license and royalty revenue and manufacturing and supply revenue.

Co-development and Research Fees

We work with our partners to co-develop pharmaceutical products. In this regard, we earn fees through performance of specific tasks, activities, or completion of stages of development defined within a contractual arrangement with the relevant partner. The nature and extent of these performance obligations, broadly referred to as milestones or deliverables, are usually dependent on the scope and structure of the project as contracted, as well as the complexity of the product and the specific regulatory approval path necessary for that product.

License and Royalty Revenue

Once a viable product opportunity is identified from our co-development and research activities with our partners, we may out-license to our partners the rights to utilize our intellectual property related to their marketing of such products globally. As a result, we earn revenue from up-front license fees received under such license, development and supply agreements. We also may earn royalties based on our partners' sales of products that use our intellectual property that are marketed and sold in the countries where we hold royalty rights pursuant to such arrangements.

Manufacture and Supply Revenue

Currently, we produce two of our partners' pharmaceutical products: Suboxone and Zuplenz. We are the exclusive manufacturer for these products. We manufacture based on receipt of purchase orders from our partners, and our partners accept delivery of these orders at shipping point. As a result, we record revenues when product is shipped and title passes to the customers. Our partners are responsible for all other aspects of commercialization of these products.

We expect future revenue from partnered activities to increase based on growing production volumes of partnered products, new product development with partners, and additional licensing of our intellectual property.

As we commercialize our proprietary CNS product candidates, beginning with Libervant and Sympazan, subject to regulatory approval, we expect to directly sell our products to consumers in the United States, resulting in an additional source of revenue which will be referred to as Product Sales, net. Additionally, we may choose to select a collaborator to commercialize our product candidates in certain markets outside of the United States. To date, we have not generated any revenues from product sales.

Costs and Expenses

Our costs and expenses are primarily the result of the following activities: generation of partnered revenues; development of our pipeline of proprietary product candidates; selling, general and administrative, including pre-launch commercialization efforts related to our CNS product candidates, intellectual property development and maintenance, and corporate management functions; and interest on our corporate borrowings. We primarily record our costs and expenses in the following categories:

Manufacture and Supply Costs and Expenses

Manufacture and supply costs and expenses are comprised of costs and expenses related to manufacturing our proprietary dissolving film products for our marketed partnered pharmaceutical products and for clinical trial batches of our proprietary and partnered product candidates, including raw

materials, direct labor and fixed overhead principally in our Portage, Indiana facility. Our material costs include the costs of raw materials used in the production of our proprietary dissolving film and primary packaging materials. Direct labor costs consist of payroll costs (including benefits) of employees engaged in production activities. Fixed overhead principally consists of indirect payroll, facilities rent, utilities and depreciation for production machinery and equipment.

Our manufacture and supply costs and expenses are impacted by our customers' supply requirements; costs of production, which includes raw materials, which we purchase at market prices and production efficiency (measured by the cost of a salable unit) which can increase or decrease based on the amount of direct labor and materials required to produce a product and the allocation of fixed overhead, which is dependent on the levels of production.

We expect our manufacture and supply costs and expenses to increase over the next several years as we commercialize and begin to market, following regulatory approval, our product candidates, including Libervant and Sympazan, our ALS product candidate, AQST-117, and our other product candidates. Additionally, we expect to incur increased costs associated with hiring additional personnel to support the increased manufacturing and supply costs arising from our commercialization of these products and product candidates. As such, we expect our manufacturing and supply costs and expenses to increase as our product candidates receive regulatory approval and can be commercialized both in and outside the United States.

Research and Development Expenses

Research and development expenses primarily consist of:

- employee-related expenses, including salaries, benefits, and travel expense;
- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, investigational sites and consultants;
- the cost of acquiring, developing and manufacturing clinical study materials; and
- costs associated with preclinical and clinical activities and regulatory operations.

We expense research and development costs as incurred.

Clinical development timelines, likelihood of success and total costs vary widely. We do not currently track our research and development costs or our personnel and related costs on an individual product basis. Furthermore, we use our research and development resources, including employees and proprietary dissolving film technology, across multiple drug development and other programs. As a result, we cannot state precisely the costs incurred for each of our research and development programs of our product candidates.

We expect our research and development expenses to increase over the next several years as we continue to implement our business strategy, expanding our research and development efforts, seeking regulatory approvals for any product candidates that successfully complete clinical trials, accessing and developing additional product candidates, and costs associated with hiring additional personnel to support our research and higher development efforts. In addition, product candidates in later stages of clinical development generally incur higher development costs that those in earlier stages of clinical development, primarily attributable to the increased size and duration of later-stage clinical trials. As such, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development, and as we add new candidates to our pipeline.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries, benefits and other related costs for executive, finance, selling and operational personnel. Other significant costs include facility and related costs not otherwise included in research and development expenses such as: professional fees for legal, consulting, tax and accounting services; insurance; selling; market research; advisory board and key opinion leaders; depreciation; and general corporate expenses.

Historically, our selling, general and administrative expenses have been focused primarily on partnered selling activities and corporate management functions. However, costs related to

commercialization of our CNS product candidates began in the second half of 2017 and are expected to accelerate in 2018, as we approach planned commercial launches. In addition, our general and administrative costs will increase as a public company, including costs related to additional personnel and accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, and investor and public relations costs.

Interest Expense

Interest expense consists of interest expense related to the Loan Agreement. Our interest is subject to changes in one-month LIBOR, and represents a monthly cash payment obligation. This debt facility is discussed in more depth in Liquidity and Capital Resources.

Other Expense

Other expense consists of non-cash changes in the fair value of warrants issued to Perceptive in connection with the Loan Agreement, loss on extinguishment of debt and loss on disposal of investment in Midatech.

Results of Operations

Comparison of Years Ended December 31, 2017 and 2016

We recorded revenue of $66.9 million and $51.8 million in 2017 and 2016, respectively, generating net losses of $8.9 million and $9.6 million for each of those years, respectively.

The following discussion of our results of operations explains the material drivers of these results of operations.

Revenues

The following table sets forth our revenue data for the periods indicated.

			Change	
	2017	2016	$	%
(In thousands, except %)				
Manufacture and supply revenue	$ 40,092	$ 37,324	$ 2,768	7%
License and royalty revenue	23,133	11,320	11,813	104%
Co-development and research fees	3,693	3,141	552	18%
Revenues	$ 66,918	$ 51,785	$ 15,133	29%

Our revenue increased 29% from $51.8 million in 2016 to $66.9 million in 2017. This increase came primarily from increases in license and royalty revenue, followed by an increase in manufacturing and supply revenue.

Manufacture and supply revenue increased approximately 7% from $37.3 million in 2016 to $40.1 million in 2017 due to higher volume demand attributable to Suboxone product sales and the launch of Zuplenz in late 2016.

License and royalty revenue increased 104% from $11.3 million in 2016 to $23.1 million in 2017. This increase was primarily related to license fees on our partnered products Suboxone and APL-130277, and royalties on Suboxone and Zuplenz. License fees were higher in 2017 as a result of the timing of milestones in these agreements, and royalties rose year-over-year on higher product sales volumes. License fees are milestone driven and may fluctuate significantly from quarter-to-quarter.

Co-development and research fees rose 18% from $3.1 million in 2016 to $3.7 million 2017. These fees are highly dependent on the timing of partnered product research and development activities and related milestones, and may fluctuate significantly quarter-to-quarter.

Expenses:

The following table sets forth our expense data for the periods indicated:

	2017	2016	Change $	Change %
(In thousands, except %)				
Manufacturing and supply	$ 19,820	$ 16,378	$ 3,442	21%
Research and development	22,133	15,450	6,683	43%
Selling, general and administrative	25,078	20,804	4,274	21%
Interest	7,707	6,143	1,564	25%
Other	1,123	2,612	(1,489)	(57%)

Manufacturing and supply costs and expenses increased 21% from $16.4 million in 2016 to $19.8 million 2017, driven by an increase in related partnered product volumes.

Research and development expenses increased 43% from $15.5 million in 2016 to $22.1 million in 2017 primarily due to increased direct project costs associated with our CNS product candidates (Libervant, Sympazan and AQST-117) and early clinical trial activity for our complex molecule product candidate AQST-108. The primary reason for the increases in costs was due to additional clinical studies of epilepsy patients at EMUs related to Libervant.

Selling, general and administrative expenses increased 21% from $20.8 million in 2016 to $25.1 million in 2017 primarily due to initial investments in our commercialization capabilities in preparation for the expected launch of Libervant, Sympazan and AQST-117. These higher costs included personnel, external consultants and other resources that enabled us to establish the key commercial functions such as sales and marketing, market access and medical affairs. We also have added additional personnel and other external resources to prepare our company for going public.

Interest expense increased 25% from $6.1 million in 2016 to $7.7 million in 2017 as a result of higher borrowings in 2017 compared to 2016, along with higher interest rates year-over-year. Our interest expense is subject to increases based on one-month LIBOR.

Other expenses decreased by 57% in 2017 compared to 2016, principally due to the change in fair value of warrants of $0.4 million, offset by one-time expense items in 2016 related to the $1.0 million loss on impairment of our Midatech investment, $0.8 million loss on the extinguishment of debt and $0.1 million of other expenses in the 2016 period that did not occur in 2017.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in January 2004, we have incurred significant losses and as of December 31, 2017, we had an accumulated deficit of $120.1 million. We have funded our operations primarily with equity and debt financings and milestone and royalty payments from our collaboration partners. Through December 31, 2017, we received net proceeds from debt and equity issuances of $125.6 million as follows:

- $50.0 million of these proceeds are from debt facilities further described below; and
- $75.6 million of these proceeds are from equity financings, with most of these proceeds received in 2008 and prior years.

We generate revenue from partnered products and related activities, but the costs to generate these revenues and the costs and expenses of our proprietary CNS and complex molecule development programs and related commercialization efforts have resulted in the deficit we have accumulated since our inception.

We had $17.4 million in cash as of December 31, 2017. We have no committed sources of capital and our borrowing capability under the Loan Agreement is fully drawn.

Credit Agreement and Guaranty

On August 16, 2016, we entered into the Loan Agreement with Perceptive. At closing, we borrowed $45.0 million under the Loan Agreement and were permitted to borrow up to an additional $5.0 million within one year of the closing date based on achievement of a defined milestone. In March 2017, we met our performance obligations under the terms of the Loan Agreement and received the remaining $5.0 million available to us under the Loan Agreement. Proceeds from the loan were used to repay an existing debt obligation of $37.5 million, with the balance available for general corporate purposes. The loan from Perceptive will mature on August 16, 2020 and bears interest, payable monthly, at one-month LIBOR or 2% plus 9.75%, subject to a minimum rate of 11.75%. The loan is interest-only through December 2018. Commencing on January 31, 2019, seven monthly principal payments are due in the amount of $550,000. Thereafter, monthly principal payments in the amount of $750,000 are due through the maturity date, at which time the full amount of the remaining outstanding loan balance is due. Our tangible and intangible assets are subject to first priority liens to the extent of the outstanding debt. Other significant terms include financial covenants, change of control triggers and limitations on additional indebtedness, asset sales, acquisitions and dividend payments. As of December 31, 2017, we were compliant with all financial and other covenants under the Loan Agreement. In addition, Perceptive received the Perceptive Warrants to purchase shares of our common stock representing 4.5% of our fully diluted common stock on an as converted basis subject to anti-dilution protections in connection with additional issuances of our common stock. The Perceptive Warrants expire on August 16, 2023.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2017 and 2016:

(In thousands)	2017	2016
Net cash provided by (used in) operating activities	$ 5,824	$ (8,175)
Net cash (used in) provided by investing activities	(2,068)	190
Net cash provided by financing activities	4,414	5,689
Net increase (decrease) in cash and cash equivalents	$ 8,170	$ (2,296)

Net Cash Provided by (Used in) Operating Activities

Net cash provided by operating activities for the year ended December 31, 2017 was $5.8 million, and was primarily attributed a net loss of $8.9 million that was offset by $7.9 million of changes in operating assets and liabilities that had the effect of providing cash in 2017 and $6.9 million in non-cash charges such as depreciation, amortization, amortization of debt issuance costs and discounts. Net cash used in operating activities for the year ended December 31, 2016 was $8.2 million, and was primarily attributed to our $9.6 million net loss and $6.3 million of changes in operating assets and liabilities that had the effect of using cash in 2016, offset by $7.7 million in non-cash charges such as depreciation, amortization, impairment of investment, amortization of debt issuance costs and loss on extinguishment of debt and changes in warrant valuation.

Net Cash (Used in) Provided by Investing Activities

Net cash used in investing activities for the year ended December 31, 2017 was attributable to capital expenditures for property, plant and equipment. Net cash provided by investing activities for the year ended December 31, 2016 was attributable to proceeds from the sale of an investment in Midatech offset by capital expenditures for property, plant and equipment. We expect our capital expenditures to increase in future periods as we launch additional proprietary and partnered products, and as we make additional investments in corporate infrastructure mostly related to information technology investments, and we expect to fund these additional investments with cash from operations.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2017 represents the proceeds of $5.0 million from the Loan Agreement, offset by debt issuance costs. Net cash provided by

financing activities for the year ended December 31, 2016 represents the proceeds from the Loan Agreement of $45.0 million, offset by the paydown of $37.5 million of existing debt and early debt extinguishment costs along with debt issuance costs on the Loan Agreement.

Funding Requirements

We believe that the net proceeds from this offering, combined with our existing cash and expected revenue from our partnered product activities, will be sufficient to fund our operations at least through the next 24 months of operations, including our planned investments in the pre-launch commercialization of our late stage CNS product candidates, research and development investments in our complex molecule product pipeline candidates, capital expenditures and investments in new product candidates in epilepsy and other CNS diseases. We have based this estimate on assumptions that could change, and we could utilize our available financial resources sooner than we currently expect. The key assumptions underlying this estimate include:

- the costs necessary to successfully complete our development efforts of our proprietary product candidates;
- continued revenue from our partnered products at levels similar to or above recent years' results;
- the levels and timing of revenues and costs to commercialize our late stage CNS product candidates; and
- the infrastructure costs to support being a public company.

We have no committed sources of additional capital. We may attempt to raise additional capital due to favorable market conditions or other strategic considerations even if we have sufficient funds for planned operations. Until we become profitable, if ever, we may need to raise additional capital in the future to further the development and commercialization of our epilepsy products, Libervant and Sympazan, our ALS product, AQST-117, and our other product candidates. We may seek to obtain additional financing in the future through the issuance of our common stock, through other public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan and cause us to delay or curtail our operations until such funding is received. To the extent that we raise additional funds by issuance of equity securities, our stockholders may experience dilution, and debt financings, if available, may involve restrictive covenants or may otherwise constrain our financial flexibility. To the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our intellectual property or grant licenses on terms that are not favorable to us. In addition, payments made by potential collaborators or licensors generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones may harm our future capital position.

If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, or reduce our planned commercialization efforts. We also may be required to evaluate partnering aspects of our proprietary product candidate programs that we currently plan to self-commercialize.

We expect to incur significant additional costs to support the obligations of a public company to various regulatory agencies, to investors and in order to comply with certain legislation and regulations, such as the Sarbanes-Oxley Act of 2002. These expenditures will include the costs of additional employees with specific skills and experiences such as SEC reporting or internal controls as well as additional costs to outside service providers such as audit, tax and legal fees.

Contractual Obligations and Commitments

Our contractual obligations relate to our debt agreement and operating leases for our facilities. The following table sets forth a summary of our contractual obligations as of December 31, 2017:

Contractual Obligations (In thousands)	Total	Less than one year	One to three years	Four to five years	After five years
Perceptive debt principal and interest	$ 57,951	$ 5,361	$ 52,590	$ —	$ —
Operating lease obligations	4,138	967	2,424	747	—
Total contractual obligations	$ 62,089	$ 6,328	$ 55,014	$ 747	$ —

Operating Lease Obligations

We have entered into various lease agreements for production and research facilities and offices. Most leases contain renewal options. Certain leases contain purchase options and require us to pay for taxes, maintenance and operating expenses. All of our leases are classified as operating leases.

Production and Research Facilities, Portage, Indiana

We lease our current production facilities in Portage, Indiana, which house certain research and development offices and current good manufacturing practices, or cGMP, manufacturing operations. The leases contain an option to purchase the facility at any time during the lease term and/or a right of first refusal to purchase the facility. In October 2017, we extended the lease in our 8,400-square-foot facility (Melton) such that it will expire in March 2023. Our second facility, a 73,000-square-foot facility (Ameriplex), has a lease, as amended, that extends through September 30, 2022 and contains a renewal option that could extend the lease through September 30, 2026.

Office and Research Facilities, Warren, New Jersey

We lease our 16,454 square-foot headquarters and principal laboratory facility in Warren, New Jersey. Through various amendments and extensions, the lease extends through February 28, 2020.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk due to changes in interest rates relates primarily to the increase or decrease in the amount of interest expense from fluctuations in one-month LIBOR associated with the Loan Agreement. For each 1% increase in one-month LIBOR in excess of 2%, our annual interest expense would increase by approximately $0.5 million. Our cash and cash equivalents are maintained in FDIC protected accounts with no exposure to material changes in interest rates. We do not purchase, sell or hold derivatives or other market risk sensitive instruments to hedge interest rate risk or for trading purposes.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of the consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements appearing elsewhere in this prospectus. We believe that the following accounting policies relating to revenue recognition, research and development expenses, inventory valuation and impairment of long-lived assets are most critical to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

Our principal source of revenue is currently derived from marketed products out-licensed to our partners. In the future, as our proprietary product candidates are approved, an additional revenue category will be product sales, net.

Revenues include the sale of our two commercialized partnered products, fees from co-development and research services, fees from licensed proprietary technologies and patent rights, and royalties based on specified product sales. Related contractual arrangements may include up-front payments, milestone payments linked to specified performance obligations, fixed monthly payments, or payments due for delivered products or services. Contracts may also include multiple-element arrangements. These are evaluated to identify deliverables and separate units of accounting. Deliverables generally represent obligations to provide analytical or testing services and reports, licenses for the use of intellectual property, manufactured products, or other performance obligations. Pursuant to FASB ASC Topic 605, *Revenue Recognition*, revenue is recognized when there is persuasive evidence of an agreement, title has passed or delivery has occurred, the price is fixed or determinable, and collection is reasonably assured.

We may enter into licensing, development and supply agreements that contain multiple deliverables. Under the provisions of FASB ASC Subtopic 605-25, *Revenue – Multiple Deliverables, Accounting for Revenue Arrangements with Multiple Deliverables*, we will evaluate whether these deliverables constitute separate units of accounting. A deliverable qualifies as a separate unit of accounting when the item delivered to the customer has standalone value and, if there is a general right of return for the items delivered to the customer, delivery or performance of the undelivered elements is considered probable and substantially in our control. Revenue from such arrangements is recognized when we have substantially completed our obligations under the terms of the arrangement and our remaining involvement is inconsequential and perfunctory. If we have significant continuing involvement under such an arrangement, fees are recognized over the estimated performance period. We recognize revenue derived from milestone payments for its research and development activities upon the achievement of specified milestones if (i) the milestone is substantive in nature, the achievement of the milestone was not reasonably assured at the inception of the agreement and achievement is linked to our performance, (ii) consideration earned relates to past and complete performance and (iii) the milestone payment is nonrefundable. Payments received in excess of amounts earned are classified as deferred revenue until earned.

Inventory Valuation

Inventories are stated at the lower of cost or net realizable value. Cost is determined on a first-in, first-out basis. Inventory includes the cost of materials, production labor and overhead. We regularly review our inventories for impairment and reserves are established when necessary. We manufacture to specific orders and do not generally manufacture for inventory or take inventory risk for finished goods and therefore believe it unlikely that significant adjustments for inventory obsolescence will take place. However, the FDA and other regulatory authorities may take action regarding certain active pharmaceutical ingredients that may cause raw material or packaging inventories to become non-usable. If our estimates for excess or obsolete inventory and its potential utility are less favorable than those projected, additional inventory reserves may be required.

Impairment of Long-Lived Assets

In accordance with the Subsections of FASB ASC Subtopic 360-10, *Property, Plant and Equipment – Overall,* long-lived assets, such as property and equipment and intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. That carrying value is considered unrecoverable if it exceeds the sum of the undiscounted cash flows expected from the use and eventual disposition of the asset.

As a result of management's evaluation of the recoverability of the carrying value of long-lived assets subject to ASC 360-10, no impairment charges were recorded for the years ended December 31, 2017 and 2016. If these estimates or their related assumptions change the fair value of these assets in the future, we may be required to record additional impairment charges.

Warrant Liability

We classify the Perceptive Warrants as a liability on our balance sheets as they are free-standing financial instruments that may require us to transfer assets upon exercise. The Perceptive Warrants were initially recorded at fair value on date of grant, and are subsequently remeasured to fair value at each balance sheet date. Changes in fair value of the Perceptive Warrants are reported in Other Expense in the statement of operations and comprehensive loss.

Pursuant to the terms of the Perceptive Warrants, the holder thereof has the right to purchase shares of our common stock representing 4.5% of our fully diluted common stock on an as converted basis.

Research and Development Costs

We expense costs associated with research and development activities as incurred. Research and development expenses include (i) employee-related expenses, including salaries, benefits, travel and share-based compensation expense, (ii) external research and development expenses incurred under arrangements with third parties, such as contract research and contract manufacturing organizations, investigational sites and consultants, (iii) the cost of acquiring, developing and manufacturing clinical study materials; and (iv) costs associated with preclinical and clinical activities and regulatory operations.

Research and development costs reflect costs for our internal proprietary research and development projects as well as costs incurred under arrangements with third parties from which we generate co-development and research fees.

Income Taxes

On December 22, 2017, the TCJA was enacted into law which overhauled the Internal Revenue Code of 1986, as amended, to revitalize our nation's economy. One significant aspect of this new legislation was to lower the U.S. Corporate tax rate from 35% to 21%. The tax reform legislation did not have a material impact on our provision for income taxes for the year ended December 31, 2017 due to the valuation allowance against our net deferred tax assets. From the period January 1, 2017 through October 31, 2017 and all of 2016, we were a Delaware limited liability company treated as a partnership for income tax purposes. From November 1, 2017 through December 31, 2017, we elected to be taxed as a C corporation. On January 1, 2018, we converted into a Delaware corporation and incorporated as Aquestive Therapeutics, Inc.

Income taxes are recorded in accordance with FASB ASC Topic 740 Income Taxes, or ASC 740, which provides for deferred taxes using an asset and liability approach. Income taxes have been calculated on a separate tax return basis. Certain of our activities and costs have been included in the tax returns filed by our predecessor company, MonoSol LLC. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Tax benefits are recognized when it is more likely than not that a tax position will be sustained during an audit. Valuation allowances are provided if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We account for uncertain tax positions in accordance with the provision of ASC 740. When uncertain tax positions exist, we recognize the tax benefit of tax provisions to the extent that the benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. To date, we have not had any significant uncertain tax positions.

Share-Based Payments

We have historically issued share-based payments pursuant to the terms of our Performance Unit Plans, or PUP Plans. The cost of employee services received in exchange for equity-based awards is determined based on FASB ASC Topic 718, *Compensation – Stock Compensation* using the grant-date fair value of the awards. Under our PUP Plans, all outstanding equity-based payments are to be recognized as an expense based on their fair value at the measurement date, which approximates our current estimated business enterprise value. Recognition of compensation expense is delayed until achievement of specified performance conditions can be considered probable. At the time that all contingencies are satisfied, the performance units granted to both employees and consultants will be reflected as liability-classified instruments based on the application of FASB ASC Topic 718.

We are a private company with no active public market for our common stock. Prior to this offering, the fair value of our performance units issued to our PUP Plans' participants was estimated on the date of grant by our board of directors. In order to determine the fair value of our performance units, our board of directors considered, among other things, timely valuations of our business enterprise value prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Practice Aide. Given the absence of a public trading market for our common units, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of the performance units, including (i) our business, financial condition and results of operations, including related industry trends affecting our operations; (ii) our forecasted operating performance and projected future cash flows; (iii) the illiquid nature of our common stock; (iv) liquidation preferences and other rights and privileges of our Preferred units; (v) market multiples of our most comparable public peers and (vi) market conditions affecting our industry.

There are significant judgments and estimates inherent in the determination of the fair value of our performance units and common stock. These judgments and estimates include assumptions regarding our future operating performance, the time to completing an IPO or other liquidity event and the determinations of the appropriate valuation methods. If we had made different assumptions, our equity-based compensation expense, net loss and net loss per share of common stock could have been significantly different.

No compensation cost was recorded in 2017 and prior years because it was not probable that the specified performance conditions under the PUP Plans would be achieved and payments would be made.

In connection with our conversion from a Delaware limited liability company to a Delaware corporation, we intend to terminate the PUP Plans. We expect this to occur in April 2018, subject to board of director and PUP Plans' participant approval. Upon termination, we will accelerate the vesting of any unvested performance units and intend to issue 60.7 million shares of non-voting common stock to compensate the performance unit holders of record on January 1, 2018. To determine the compensation expense associated with the termination of the PUP Plans and the issuance of shares of non-voting common stock, we engaged a valuation consultant to prepare an estimate of our enterprise value and the fair value of each series of our capital stock and equity instruments as of the date of termination. Such valuation yielded value of $0.168 per share of non-voting common stock after considering the nature of these shares and the enterprise value of the business. The valuation utilized for this purpose was developed in accordance with the Practice Aide.

We will recognize compensation cost and related taxes of approximately $14.9 million in general and administrative expense in the second quarter of 2018 upon issuance of the shares of non-voting common stock.

Recent Accounting Pronouncements

Refer to Note 2. "Summary of Significant Accounting Policies" in the accompanying notes to our consolidated financial statements appearing elsewhere in this prospectus for a discussion of recent accounting pronouncements.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was enacted. The JOBS Act provides that, among other things, an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. As an emerging growth company, we have elected to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public emerging growth companies.

In addition, we intend to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, if as an “emerging growth company” we intend to rely on such exemptions, we are not required to, among other things, (i) provide an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, and (iii) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer’s compensation to median employee compensation. These exemptions will apply for a period of five years following the consummation of this offering or until we no longer meet the requirements of being an emerging growth company, whichever is earlier.

BUSINESS

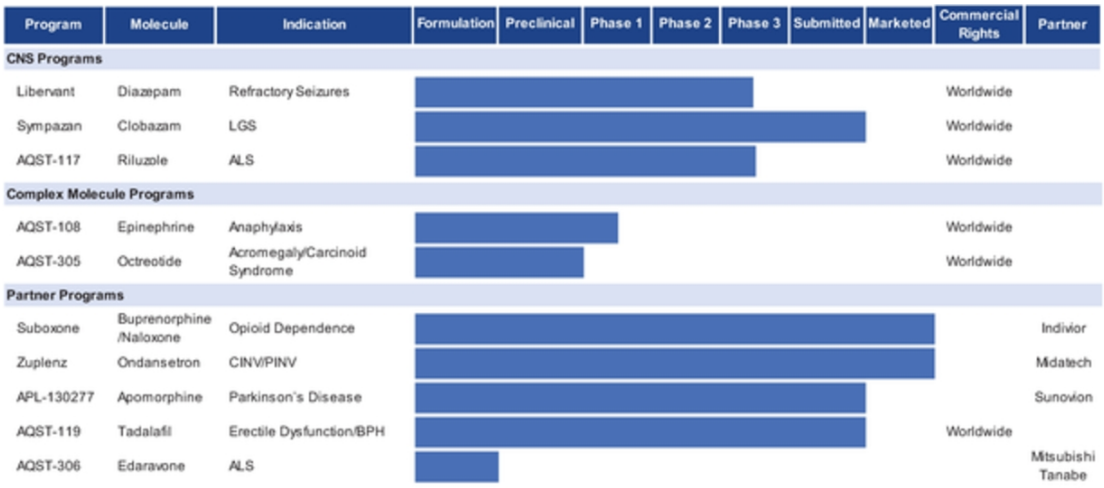
Overview

We are a specialty pharmaceutical company focused on identifying, developing and commercializing differentiated products to address unmet medical needs. We have a late-stage proprietary product pipeline focused on the treatment of diseases of the Central Nervous System, or CNS. We believe that the characteristics of these patient populations and shortcomings of available treatment options create opportunities for the development and commercialization of meaningfully differentiated medicines. Our most advanced proprietary product candidates, which we intend to commercialize ourselves, include (i) Libervant, a buccal soluble film formulation of diazepam for the treatment of recurrent epileptic seizures, for which we expect to submit a New Drug Application, or NDA, in 2018; (ii) Sympazan, an oral soluble film formulation of clobazam for the treatment of seizures associated with a rare, intractable form of epilepsy known as Lennox-Gastaut Syndrome, or LGS, for which we submitted an NDA in October 2017 and have been given an August 31, 2018 Prescription Drug User Fee Act, or PDUFA, date, which is the date the U.S. Food and Drug Administration, or FDA, expects to complete its review of our NDA, and (iii) AQST-117, an oral soluble film formulation of riluzole for the treatment of Amyotrophic Lateral Sclerosis, or ALS, for which we expect to submit an NDA in 2018. We have also developed a proprietary pipeline of complex molecule products addressing large market opportunities beyond CNS indications, which include (i) AQST-108, a sublingual film formulation of epinephrine for the treatment of anaphylaxis, for which we expect to begin additional Phase 1 trials in 2018 and (ii) AQST-305, a buccal film formulation of octreotide for the treatment of acromegaly and neuroendocrine tumors, for which we expect to begin human proof of concept trials in 2018.

In addition to these product candidates, we have a portfolio of commercialized and development-stage partnered products. These products include Suboxone, a sublingual film formulation of buprenorphine and naloxone, which is the market leader for the treatment of opioid dependence. We manufacture all of our partnered and proprietary products at our FDA and Drug Enforcement Agency, or DEA, inspected facilities and anticipate that our current manufacturing capacity is sufficient for commercial quantities of our products and product candidates currently in development. We have produced over 1.2 billion doses of Suboxone in the last four years. Our products are developed using our proprietary PharmFilm technology and know-how. Our patent portfolio currently comprises at least 200 issued patents worldwide, of which at least 40 are U.S. patents, and more than 75 pending patent applications worldwide.

Our Product Portfolio and Pipeline

The following table outlines our pipeline of product candidates:



Proprietary CNS Product Portfolio

We have initially focused our proprietary product pipeline on certain difficult to treat CNS diseases. Our PharmFilm technology allows us to develop medicines that offer non-invasive delivery, customized suitability for patients with dysphagia, or trouble swallowing, can be administered without water and ensure consistent therapeutic dosing. We believe that these characteristics will allow us to achieve the desired patient outcomes, while potentially reducing the total cost of patient care.

The most advanced assets within our proprietary CNS portfolio are as follows:

- **Libervant** – a buccally, or inside of the cheek, administered soluble film formulation of diazepam, a benzodiazepine used as a rescue therapy for breakthrough epileptic seizures and an adjunctive therapy for use in recurrent convulsive seizures. We are developing Libervant as an alternative to Diastat (diazepam rectal gel), the current standard of care rescue therapy for patients with epilepsy, which as a rectal gel, is invasive, inconvenient, and difficult to administer. As a result, a large portion of the patient population does not receive adequate treatment or foregoes treatment altogether. We believe that Libervant will enable a larger share of patients to receive more appropriate treatment by providing consistent therapeutic dosing in a non-invasive and innovative treatment form for epileptic seizures. Libervant is currently completing its final clinical trials. We expect to submit an NDA for Libervant in 2018.
- **Sympazan** – an oral soluble film formulation of clobazam, a benzodiazepine used as an adjunctive therapy for seizures associated with LGS. We are developing Sympazan as an alternative to Onfi (clobazam), currently available in either tablet form or liquid suspension. LGS patients often have difficulty swallowing pills and large volume suspensions leading to uncertain and inconsistent dosing and increasing the burden of care, particularly for patients that may be combative or resistant to treatment. We believe that Sympazan will address these treatment obstacles because it is mucoadhesive, dissolves rapidly in existing saliva and is swallowed along with a patient's natural saliva production, and therefore cannot be easily spit out. In clinical trials, Sympazan has demonstrated bioequivalence to Onfi. We submitted an NDA for Sympazan in October 2017 and were given a PDUFA date of August 31, 2018. If approved by the FDA, we anticipate launching Sympazan by the end of 2018.
- **AQST-117** – an oral soluble film formulation of riluzole, a small molecule glutamate antagonist used as an adjunctive therapy in the treatment of ALS, which has been shown to slow disease progression, increase lifespan and improve quality of life. However, because ALS patients typically have difficulty swallowing, tablet administration is challenging. We are developing AQST-117 as an alternative to Rilutek (riluzole), which is currently available only in tablet form in order to achieve an easier, more reliable and accurate dosing. This may allow patients to continue therapy even after their ability to swallow has become compromised. AQST-117 addresses these treatment obstacles because it is mucoadhesive and dissolves easily on the tongue without the need for water and without a substantial increase in salivary flow. In clinical trials, AQST-117 has demonstrated bioequivalence to Rilutek. We expect to submit an NDA for AQST-117 in 2018.

Proprietary Complex Molecule Portfolio

We are utilizing our technology and know-how to target large market opportunities by developing orally-administered complex molecule therapies as alternatives to invasively-administered standard of care injectable therapeutics. We currently have two active complex molecule programs in clinical development. The first is focused on the oral delivery of the hormone epinephrine. The second is focused on the delivery of a peptide known as octreotide. Octreotide would be the first peptide delivered orally using our technology and may create other opportunities for peptides and biologics.

The two active programs in our complex molecule portfolio are:

- **AQST-108** – a sublingual film formulation of epinephrine that we are developing for the treatment of anaphylaxis, a severe and potentially life-threatening allergic reaction. Epinephrine is the standard of care in the treatment of anaphylaxis and is currently administered via intramuscular injection. The current market leader is EpiPen, a single-dose, pre-filled automatic injection

device. As a result of its administration via intra-muscular injection, many patients and their caregivers are reluctant to use currently available products, resulting in increased hospital visits and overall cost of care to treat anaphylactic events. We are designing AQST-108 to be the first non-injectable form of epinephrine used to treat anaphylaxis. We believe that, as a result of its sublingual administration, AQST-108 will improve patient compliance and lower the total cost of care. AQST-108 has shown promising results in one human proof of concept trial. We are currently optimizing the formulation for Phase 1 trials, which we expect to begin in 2018.

- **AQST-305** – a sublingual film formulation of octreotide, a small peptide that has a similar pharmacological profile to natural somatostatin, for the treatment of acromegaly, as well as severe diarrhea and flushing associated with carcinoid syndrome. Acromegaly is a hormone disorder that results from the overproduction of growth hormone in middle-aged adults. Octreotide is the standard of care for the treatment of acromegaly. The current market leader, Sandostatin, is administered via deep subcutaneous or intramuscular injections once a month. This monthly treatment regimen can result in loss of efficacy towards the end of the monthly treatment cycle. We are developing AQST-305 as a non-invasive, pain-free alternative to Sandostatin to reduce treatment burden, healthcare costs and the potential loss of efficacy over the treatment cycle. AQST-305 has shown promising preclinical results. We initiated a development program to demonstrate human proof-of-concept and expect to dose the first patient in 2018.

Partnered Products

Our portfolio also includes products and product candidates that we have partnered, or will seek to partner, for commercialization. In the year ended December 31, 2017, our partnered product portfolio generated over $1 billion in revenue for our partners, resulting in $66.9 million in revenue to us. Our key partnered products and products that we intend to partner include:

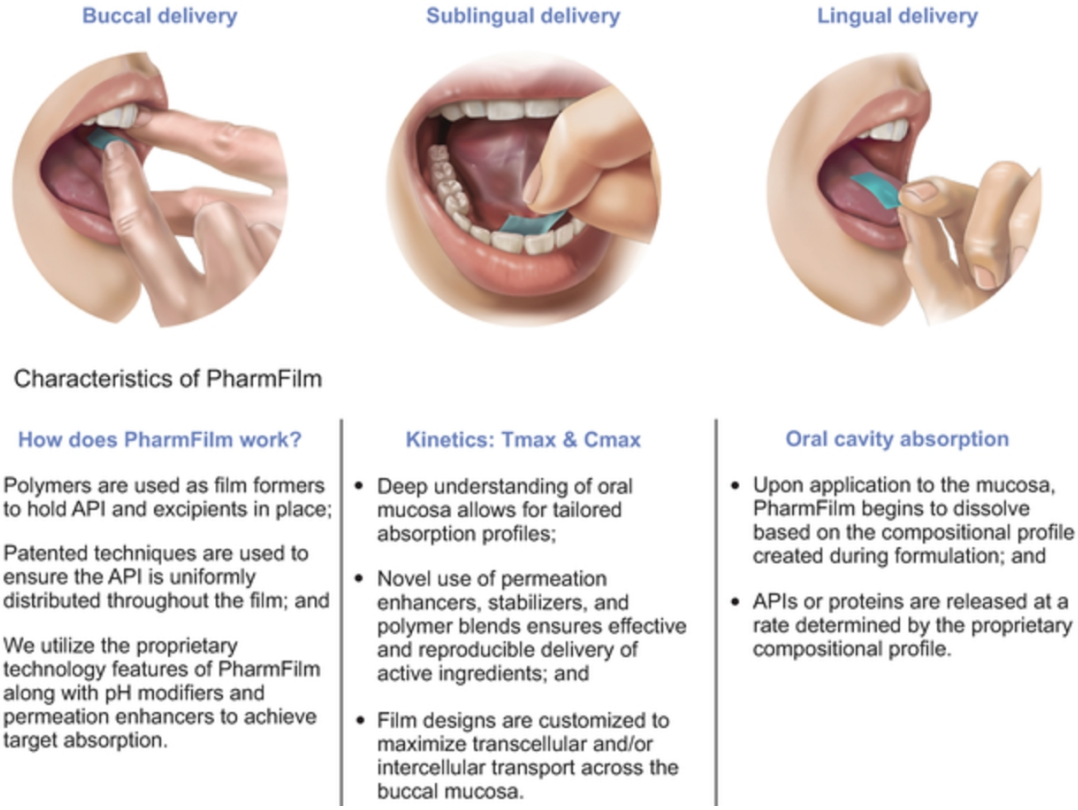
- **Suboxone** – a sublingual film formulation of buprenorphine and naloxone that is marketed in the United States and internationally for the treatment of opioid dependence. Suboxone Sublingual Film was launched in partnership with Indivior Inc., or Indivior, in 2010. Suboxone Sublingual Film is the most prescribed branded product in its category and is the first sublingual film product for the treatment of opioid dependence with approximately 60% market share despite multiple competitors, including alternative dosing formulations. We are the sole supplier and manufacturer of Suboxone Sublingual Film. In the past four years, we have produced over 1.1 billion doses of Suboxone.
- **APL-130277** – a sublingual film formulation of apomorphine, which is a dopamine agonist in development to treat episodic off-periods in Parkinson's disease. APL-130277 is being developed as a sublingual alternative to injectable form of apomorphine. We licensed intellectual property for APL-130277 to Cynapsus Therapeutics, a company that was acquired by Sunovion Pharmaceuticals Inc., or Sunovion. APL-130277 has successfully completed Phase 3 clinical studies. Sunovion, our partner and sponsor of APL-130277, submitted an NDA to the FDA on March 29, 2018.

PharmFilm – Our Oral Film Technology

We are the worldwide leader in oral film drug delivery and manufacturing. We supply more than 95% of the world's oral films for prescription pharmaceutical use, and we have the capability to produce more than one billion commercial doses a year. We developed our PharmFilm technology to provide meaningful clinical and therapeutic advantages over other existing dosage forms and, in turn, to improve the lives of patients and caregivers. PharmFilm is protected by our patent portfolio, which currently comprises at least 200 issued patents worldwide, of which at least 40 are U.S. patents, and more than 75 pending patent applications worldwide. Several of the patents in this intellectual property portfolio are utilized in each of our proprietary pipeline products. We are continuing to develop additional intellectual property and know-how related to the applications and engineering of PharmFilm alone or in combination with other technologies to create product capabilities that have compelling value propositions.

PharmFilm is comprised of proprietary polymer compositions that serve as film formers to hold active pharmaceutical ingredients, or APIs, and excipients in place. Proprietary and patent-protected

compositions, formulation and manufacturing techniques and technology are employed to ensure that the API is distributed uniformly throughout the film and that target absorption levels are achieved. Our proprietary technology and manufacturing process ensures that PharmFilm can be engineered to fit a variety of target product profiles in order to best address the unmet patient need present within specific disease states. PharmFilm, which is similar in thickness and size to a postage stamp, can be administered via buccal, sublingual or lingual oral delivery.



We believe the innovative nature of our PharmFilm drug delivery platform has the potential to offer a number of meaningful advantages to patients, caregivers and physicians compared to current standard of care therapies, including:

- preferred alternative to more invasive drugs such as injection;
- faster onset of action;
- direct absorption into the bloodstream reducing or avoiding “first pass” effects in the liver;
- reduced gastrointestinal, or GI, side effects;
- positive dosing outcomes, especially for patients with physical (*e.g.*, dysphagia) or psychological barriers to other methods of drug administration;
- stable, durable, portable and quick-dissolving (with or without water);
- customizable delivery routes for tailored pharmacokinetic, or PK, profiles (buccal, sublingual or lingual); and
- customizable taste profiles.

We chose to initially focus our development efforts on the CNS market because we believe the application of PharmFilm is particularly valuable and relevant to patients suffering from certain CNS

disorders where there are unmet patient needs or shortcomings in current standards of care. We believe there remains significant opportunity to develop additional products in the CNS market. Additionally, our know-how and proprietary position have broad application beyond CNS, and we plan to explore the applications of PharmFilm in other disease areas.

Our Management Team

Our management team is a critical component to the development of our business model and the execution of our strategy. We are led by executives with an average of over 17 years of relevant senior leadership experience, including developing and commercializing branded and generic pharmaceuticals at large multinational pharmaceutical companies such as Johnson & Johnson, GlaxoSmithKline PLC and Novartis AG. Additionally, our team has significant experience in commercialization of pharmaceutical products, translational science, drug evaluation, clinical development, regulatory affairs and business development. Our management team is supervised and supported by a board of directors with expertise in finance, strategy, medicine and drug development.

Our Strategy

We are a patient-centric pharmaceutical company developing and commercializing products that address unmet needs and improve the lives of patients and their caregivers. We focus on developing medicines for patient populations suffering from the shortcomings of available treatment options, which can create an opportunity for differentiated medicines. Our pipeline is initially focused on developing treatments for CNS diseases, as well as orally administered complex molecules that we believe can be alternatives to invasively-administered standard of care therapies. Our strategy leverages our global intellectual property portfolio, know-how, demonstrated research and development capabilities and proprietary manufacturing platform.

To achieve these goals, our strategy includes the following key elements:

- ***Advance our late stage proprietary portfolio of CNS product candidates to solve critical healthcare problems and make a meaningful improvement in the lives of patients and caregivers.*** We have three proprietary CNS product candidates for which we have completed or are approaching NDA submission. These product candidates address treatment challenges associated with epilepsy and ALS. We have submitted an NDA to the FDA and were given a PDUFA date of August 31, 2018 for Sympazan. We expect to submit NDAs for Libervant and AQST-117 in 2018.
- ***Scale our commercial platform to maximize the value of our proprietary product candidates.*** In order to maximize the value of our proprietary product candidates, we plan to self-commercialize our late stage CNS and other proprietary product candidates through a dedicated and focused commercial organization. We have built expertise in marketing, sales, payor and market access management and medical affairs in anticipation of multiple product launches starting in 2018. Based on overlapping prescriber call points for our initial CNS product candidates, we believe an efficient and dedicated sales force can effectively cover the vast majority of targeted prescribers.
- ***Exploit our technology and know-how to develop oral versions of more complex injectable drugs to address unmet patient needs.*** Based on promising preclinical and early clinical results, we intend to continue to develop oral transmucosal versions of epinephrine and octreotide, products that are currently available only in injectable form. We believe the success of these efforts may lead to additional high value opportunities in developing oral transmucosal versions of some proteins, peptides and other complex molecule drugs, which have historically been administered by means other than oral intake, such as injection or infusion.
- ***Continue to identify product opportunities within CNS and other markets to expand our proprietary product pipeline.*** We intend to identify additional product candidates that provide clinical differentiation and solve unmet needs. In the CNS space, we will leverage our

relationships with key stakeholders including patients, caregivers, key opinion leaders and patient advocacy groups to identify new product opportunities. Additionally, we will continue to evaluate other therapeutic areas, indications and products where our expertise and know-how can create differentiation and value.

- ***Acquire products or establish partnerships to develop and market products utilizing new chemical entities.*** We intend to continue to strategically expand our product portfolio by developing products that incorporate new chemical entities to treat disorders with high unmet need. For example in August 2017, we entered into a partnership with Mitsubishi Tanabe relating to edaravone, a treatment for ALS currently marketed only in injectable form.
- ***Continue to expand and solidify our intellectual property portfolio for our products, product candidates and manufacturing processes.*** Our robust global intellectual property portfolio is a significant source of competitive advantage, the strength of which has been demonstrated through multiple successful patent defenses. We have built a two-tier patent estate consisting of composition-of-matter and method of manufacture patents and patent applications. We intend to expand our intellectually property estate as we advance our PharmFilm and other technologies and as we develop new and existing product candidates.

Market Overview

CNS Market

CNS diseases affect the brain or spinal cord, and cause neurological and psychiatric disorders. Driven by an increase in mental health awareness and an aging population, the global market for therapeutics indicated for CNS disorders was estimated by EvaluatePharma to be $80 billion in 2017, with anticipated growth to $96 billion by 2022.

Epilepsy

Epilepsy is a chronic CNS disorder characterized by recurrent seizure activity. There are approximately 3.4 million people in the United States suffering from epilepsy. According to IQVIA, antiepileptic medications generated sales of $4.4 billion in the United States in 2017. The direct (medical) and indirect (lost wages and productivity) annual costs associated with epileptic patients in the United States are estimated to be approximately $15.5 billion.

Epilepsy treatment regimens typically consist of chronic and acute management therapies. Chronic medicines are used on a daily basis to suppress seizure activity. Approximately 1.2 million of those 3.4 million people suffering from epilepsy will continue to suffer with breakthrough seizures and require an acute (rescue) management strategy. Patients are routinely prescribed antiepileptic drugs, or AEDs, as “maintenance” therapy to control chronic seizure activity. Most AEDs specifically target neuronal excitation or neuronal inhibitory pathways. There are currently more than 20 AEDs approved for use in the United States, and therapeutic choice depends on the epileptic syndrome being considered. Patients are routinely prescribed benzodiazepines as “rescue” therapy for the management of acute seizure emergencies.

Rescue therapies are administered as needed in the event of an acute seizure to rapidly terminate seizure activity. One of the most effective benzodiazepines currently available for the treatment of acute seizures is diazepam. Diazepam is currently marketed as Diastat, a product administered rectally. Although Diastat is the preferred drug prescribed by physicians, due to its rectal administration, Diastat presents a particular challenge for patients. As a result, only approximately 100,000 patients out of 1.2 million sufferers currently use this therapy. The remaining sufferers either pursue less effective treatments or forego treatment altogether.

There are multiple epileptic syndromes including LGS, which is a rare, intractable form of epilepsy and affects approximately 55,000 patients in the United States. Patients with LGS are often drug resistant, predisposing them to recurrent seizures, and are typically prescribed a combination of antiepileptic medications, which often includes clobazam. Clobazam is currently marketed under the brand name Onfi and is available in both a tablet and suspension formulation. Onfi generated combined sales revenue of $753 million with more than 475,000 prescriptions filled in 2017, and is expected to lose patent protection in October 2018.

We are developing our lead product candidates, Libervant and Sympazan, to reduce the burden associated with administering both chronic and rescue therapies, thereby improving patient compliance and lowering the overall cost to the healthcare system for epileptic patients.

Amyotrophic Lateral Sclerosis

ALS is a progressive neurodegenerative disease affecting nerve cells responsible for controlling voluntary muscle movement. Patients suffering from ALS have progressive degeneration of motor neurons, which ultimately leads to death, primarily due to respiratory failure. Diagnosis of ALS typically occurs between the ages of 40 and 60, with more than 13,000 patients diagnosed in the U.S. each year, which corresponds to a prevalence of four cases per 100,000 people. According to IQVIA, ALS medications generated sales of $62 million in the U.S. in 2017.

There are currently no treatments available that reverse the damage caused by ALS. However, there are two treatment molecules that have been shown to slow disease progression, riluzole marketed as Rilutek and edaravone marketed as Radicava. According to IQVIA, the combined market for riluzole generated over 62,000 prescriptions and sales of $7 million in 2017.

In addition to therapeutics aimed at slowing disease progression, patients are often prescribed multiple medications and receive additional therapies, including breathing care, physical therapy, occupational therapy, speech therapy, nutritional support, and psychological and social support, to ease the burden of the disease.

As a result of the degenerative muscle function associated with ALS, patients eventually lose the ability to swallow. Because riluzole may slow disease progression and delay the need for a tracheotomy, dysphagia represents a barrier to treatment for many of these patients. We are developing AQST-117 to allow patients to remain on riluzole therapy for extended periods of time, delaying the need for procedures like tracheotomies, prolonging the quality of life for those patients and lowering the overall cost of treatment.

Other Therapeutic Areas

In addition to products to treat CNS conditions, we are developing a number of product candidates in other therapeutic areas, such as anaphylaxis and acromegaly to create differentiated medicines to address unmet needs.

Anaphylaxis

Anaphylaxis is a systemic allergic reaction caused by a wide range of allergen exposure, estimated to affect one in 50 people in the United States. Anaphylaxis typically occurs quickly once allergen exposure has occurred, and if untreated, can lead to death via airway restriction. According to IQVIA, anaphylaxis treatments generated sales of $1.7 billion in the U.S. in 2017.

Treatment of anaphylaxis typically consists of an intramuscular injection of epinephrine administered at the earliest opportunity, followed by additional intramuscular or intravenous injections as needed. While generic versions of epinephrine are currently available, they are provided as a vial of medication administered via syringes. Due to the inconvenience of this dosing mechanism, a branded form of epinephrine known as the EpiPen, which utilizes a proprietary auto-injector device administered through a deep intramuscular injection, dominates the market. In addition, recent manufacturing issues that resulted in injector malfunctions have led to significant patient concern regarding the reliability of auto-injectors. According to IQVIA, branded and generic versions of epinephrine auto-injectors generated over 3.8 million prescriptions and combined gross sales of $1.5 billion in 2017. EpiPen, which is marketed by Mylan, represents over 74% of the current market on a prescription volume basis.

Proper dosing and the ability to effectively administer epinephrine in a timely, reliable manner is critical for patients experiencing anaphylaxis. However, the inability to administer complex molecules via oral administration has limited the development of treatments that have the potential to provide significant patient benefit. We designed AQST-108 to offer a more convenient and cost effective oral form of epinephrine as an alternative to the current standard of care.

Acromegaly

Acromegaly is a hormone disorder that results from the overproduction of growth hormone in middle-aged adults. The condition is typically caused by a benign tumor present in the pituitary gland that excretes excessive amounts of growth hormone and leads to exaggerated bone growth over time. Due to the gradual progression of the disorder, patients are often not diagnosed for years. The prevalence of acromegaly is estimated to be 78 cases per million people, indicating approximately 25,000 diagnosed patients within the United States. According to IQVIA, acromegaly treatments generated sales of $1.2 billion in the United States in 2017.

Depending on the placement and size of the tumor, patients may be eligible for endoscopic transnasal transsphenoidal surgery, a procedure in which pituitary tumors are removed through the nose and sphenoid sinus. However, surgeons may be unable to completely remove the tumor, leading to persistently elevated growth hormone levels post-surgery. The standard of care for post-surgery patients includes the use of somatostatin analogues to lower production or block the action of growth hormones. The somatostatin analogues currently available, octreotide and lanreotide, are administered by deep subcutaneous or intramuscular injections once a month, or subcutaneous injections three times daily.

The market leading product for acromegaly is octreotide, which is marketed as Sandostatin LAR by Novartis, and is administered monthly via depot injections. According to IQVIA, Sandostatin generated over 49,000 prescriptions and sales of $843 million in 2017.

Ease of administration has been identified as an unmet patient need within this market, with at least one other company pursing an oral formulation of octreotide. Our PharmFilm formulation has the potential to reduce treatment burden and healthcare costs for patients, and improve clinical differentiation.

Proprietary CNS Product Candidates

Libervant (Diazepam)

Product Overview

Libervant is a buccal soluble film formulation of diazepam in development as a rescue therapy for patients with epilepsy who are already taking antiepileptic medications, and who require occasional use of diazepam to control bouts of increased seizure activity. We expect to submit an NDA for Libervant in 2018. Libervant has been granted orphan drug designation and has been granted fast track designation.

Limitations of Current Therapies

Approximately 1.2 million of the 3.4 million people suffering from epilepsy will continue to suffer with breakthrough seizures and require an acute (rescue) management strategy. Many patients who suffer from severe epilepsy and experience refractory or breakthrough seizures are managed sub-optimally with current therapies, and in some cases chose not to be prescribed any therapies due to the limitations of the currently marketed rectal product. The standard of care therapy, Diastat, is particularly difficult to administer and presents challenges for both patients and caregivers. Difficulties associated with rectal administration of Diastat include patient dignity and respect, inaccurate dosing due to leakage of rectal gel, invasiveness of treatment, inconvenience, time required to administer the drug, and ability of non-primary caregivers to effectively administer Diastat in the event a primary caregiver is not present. As a result of these challenges, only about 250,000 doses of Diastat are prescribed per year, despite a much larger population of patients suffering from epilepsy who would potentially benefit from a rescue therapy.

Additionally, there is a population of epilepsy patients who do not achieve adequate blood plasma concentration of diazepam following administration of Diastat. We refer to these patients as Diastat “non-responders”. Although this population represents a relatively small portion of the market, these patients are similarly underserved, and are currently prescribed therapies that are considered less effective than Diastat.

Our Solution

We are developing Libervant as an alternative to Diastat. As an easily administered buccal film product that quickly dissolves when applied to the buccal mucosa, Libervant has a rapid onset of action and provides a consistent therapeutic dosing. We believe Libervant has the potential to address many of

the dosing and administration issues facing patients who are currently prescribed Diastat and to become the standard of care therapy for patients. Libervant also uses less diazepam to achieve desired treatment results. We believe Libervant has the potential to expand the population of epilepsy patients who are prescribed rescue therapies to include high functioning teens and adults who otherwise chose not to use Diastat and instead manage their symptoms with extra maintenance doses of their oral therapies before or after they experience a seizure. An oral product with fast onset of action could be a better rescue therapy option to these patients. In market research studies we have performed, patients, caregivers, and physicians have all indicated high receptivity to an oral alternative to Diastat.

We also believe that Libervant has the potential to be effective in the Diastat “non-responders” population. In studies to date, Libervant has shown consistent blood plasma concentrations in volunteers that did not obtain expected diazepam levels using Diastat.

Clinical Development

Our clinical trials were designed under a Section 505(b)(2) pathway in consultation with the FDA, and included a dose proportionality study in healthy adults designed to demonstrate dose proportional blood plasma levels for Libervant at 5, 10 and 15 mg doses; a pivotal bioavailability study in healthy adults designed to compare the PK and demonstrate bioavailability of Libervant to Diastat; a food effect study; adult and pediatric Epilepsy Monitoring Unit, or EMU, studies in patients with epilepsy designed to compare the PK of Libervant in subjects with epilepsy in the interictal condition, when they are not experiencing seizures, versus the ictal/peri-ictal condition, when they are experiencing seizures; and a long-term safety study in children, adolescents and adults to assess the safety and tolerability of chronic intermittent use of Libervant by examining any pathological changes in the oral mucosa and gustatory cavity.

In March 2018, we received interim data from our adult EMU clinical study for Libervant. Through February 2018, 12 subjects had completed the study across the two treatment arms. This represents 40% of the 30 subjects needed to complete the study. Preliminary analysis of the data indicates the following:

- A 12.5mg of Libervant administered during an interictal, or non-seizure, state and without regard to food (n=12 patients) provided appropriate maximal plasma concentrations of diazepam (Cmax) within 60 minutes of administration (Tmax). Furthermore, similar Cmax and Tmax levels were obtained during dosing in a peri-ictal state. We believe these results successfully demonstrate that Libervant adequately absorbed into the blood stream regardless of whether it is applied during a seizure or normal state.
- Observed plasma levels of diazepam in patients with epilepsy were lower than plasma levels in healthy volunteers at the same dose level. This is consistent with the effects of multiple concomitant AEDs, which interact with diazepam and are commonly used by these patients.
- Based on these data, we currently anticipate that a 12.5mg dose of Libervant will be equivalent to a 17.5mg dose of Diastat. As a point of reference, our 12.5mg Libervant in patients with epilepsy had a similar Cmax to a 12.5mg dose of Diastat given to healthy volunteers with no exposure to AEDs. We believe this confirms our ability to provide an efficacious dose of Libervant at a lower dose level than Diastat.

We are in the process of requesting a face-to-face meeting with the FDA where these data, along with other clinical data, will be presented. We believe the interim data support our view that, upon the completion of our adult EMU study, we will have the necessary supporting data to submit a marketing application to the FDA.

Sympazan (Clobazam)

Product Overview

Sympazan is an oral soluble film formulation of clobazam, a benzodiazepine that is used as an adjunctive therapy for seizures associated with LGS. We submitted an NDA to the FDA in October 2017 and were given a PDUFA date of August 31, 2018. If approved by the FDA, we anticipate launching Sympazan by the end of 2018.

Limitations of Current Therapies

Patients with LGS are often drug resistant, predisposing them to recurrent seizures, and are typically prescribed a combination of antiepileptic medications, which often includes branded clobazam. Clobazam is currently marketed by Lundbeck under the brand name Onfi and is available in both a tablet and suspension formulation.

Medication administration is perceived to be a significant unmet need for LGS caregivers and patients. Approximately 30-40% of LGS patients experience dysphagia making more traditional administration routes a significant burden on the patient. Additionally, some patients refuse to swallow tablets due to physical limitations of the disease, behavioral or compliance issues. While some caregivers will crush the tablets to make dosing easier or use a suspension formulation that is squirted into the mouth, these methods do not always ensure that the patient receives the full, correct dose. Further, suspension dosage forms require significant volume, often result in an unpleasant taste and can be easily spit out by non-compliant patients.

Our Solution

We are developing Sympazan to offer patients a well-known antiepileptic medication in a formulation that could improve ease of use, dosing completeness and tolerability. We believe that Sympazan offers advantages over other clobazam dosage forms in patients with LGS. Specifically, we have developed Sympazan as a mucoadhesive, rapidly dissolving, easy to swallow film that cannot be easily spit out by non-compliant patients once placed in the mouth. We also believe that Sympazan alleviates the concerns of excessive volume and unpalatable taste associated with traditional suspension dosage forms, as well as alleviating the burden of care, potentially for patients that may be combative or resistant to treatment. We believe a significant market opportunity exists for a form of clobazam with these advantages. In various comparison studies of Sympazan, physicians, caregivers and patients have expressed a preference for our soluble film formulation over traditional forms of clobazam.

Clinical Development

Our clinical development of Sympazan has followed the 505(b)(2) regulatory pathway. Beginning in 2016 we conducted two clinical trials studying Sympazan in LGS. The first, the pilot study, evaluated PK in healthy volunteers and the second, the pivotal study, demonstrated bioequivalence to the reference listed drug Onfi. We submitted an NDA to the FDA with a target indication of LGS in October 2017. This NDA has a PDUFA date of August 31, 2018.

Additionally, given the broad applicability of the molecule and strong prescriber preference across a range of indications, we may develop and submit Sympazan for approval in additional indications in the future.

AQST-117 (Riluzole)

Product Overview

AQST-117 is an oral soluble film formulation of riluzole, a small molecule glutamate antagonist used as an adjunctive therapy in the treatment of ALS, which has been shown to slow disease progression, increase lifespan and improve quality of life. AQST-117 has been granted orphan drug designation.

Limitations of Current Therapies

ALS is a neurodegenerative disorder that involves gradual breakdown of motor neurons leading to muscle weakness, disability, and ultimately death. The U.S. prevalence of ALS is 4 cases per 100,000 persons, though higher prevalence rates are seen among specific age and ethnic groups. Disease progression leads to muscle atrophy, including loss of ability to swallow. Riluzole is currently marketed by Covis Pharma under the brand name Rilutek and has been subject to generic competition since June 2013 and is currently available in a tablet formulation.

As a result of the degenerative muscle function associated with ALS, patients eventually lose the ability to swallow. Dysphagia represents a barrier to treatment for many of these patients, with medication

administration resulting from dysphagia representing a significant unmet need for ALS caregivers and patients. The longer patients are able to remain on riluzole therapy, which has been shown to slow the progression of ALS, more invasive and costly treatments, such as tracheotomies, can be delayed, thus improving patients' quality of life.

Our Solution

We have developed AQST-117 as an alternative to the existing riluzole therapy (Rilutek), which is currently available only in tablet form. AQST-117 allows ALS patients, who suffer dysphagia as a core symptom of their progressing disease, to achieve more reliable and accurate dosing and to continue therapy even after their ability to swallow is compromised. We believe this improved administration may lead to improved outcomes in ALS patients.

Clinical Development

We have completed a pilot PK and pivotal PK study for AQST-117. In addition we have completed a food effect study. All of these studies have successfully shown bioequivalence to the reference listed drug, Rilutek. We are currently conducting a 12-week safety study in approximately 30 subjects with ALS as well as a swallowing study in approximately 25 subjects with ALS. Based on our interactions with the FDA, we believe that the completion of these studies may represent the final data required for the submission of an NDA to the FDA via the 505(b)(2) pathway. We expect to submit an NDA for AQST-117 in the treatment of ALS in the middle of 2018.

Proprietary Complex Molecule Candidates

AQST-108 (Epinephrine)

Product Overview

AQST-108 is a sublingual film formulation of epinephrine that we are developing for the treatment of anaphylaxis, a severe and potentially life-threatening allergic reaction. AQST-108 is currently in Phase 1 clinical development, and we expect to initiate another Phase 1 study with an optimized formulation of AQST-108 in the middle of 2018.

Limitations of Current Therapies

Anaphylaxis is a severe systemic allergic reaction that can be triggered by certain foods, insect stings, certain medications and latex, among other allergens. Signs and symptoms of anaphylaxis typically occur within seconds or minutes of exposure and may include low blood pressure, skin rash or itching, constriction of the airway and difficulty breathing and nausea and vomiting. If not treated immediately, anaphylaxis can lead to death due to airway restriction or cardiac arrest. Anaphylaxis affects an estimated one in fifty people in the United States across a range of allergens.

The standard of care for anaphylaxis is epinephrine, a non-selective adrenergic agonist, which is administered via intramuscular injection. Because anaphylaxis can progress quickly, the ability to administer a reliable and accurate dose of epinephrine as quickly as possible following a reaction is critical for patient recovery and survival. Epinephrine typically comes in a single-dose, pre-filled automatic injection device, or an auto-injector. People with known allergies and who are at risk for anaphylaxis are advised to carry an auto-injector with them at all times and self-administer at the first signs of an anaphylactic reaction. The EpiPen and similar products are inconvenient to transport and many patients and caregivers dislike injections as a delivery method. Additionally, injector malfunction issues and user administration errors may prevent successful and timely dosing which can result in danger to patients.

Our Solution

We are developing AQST-108 as an alternative to the currently marketed intramuscular injections. We believe there is a market opportunity for a non-injectable, easier to administer product with a fast onset of action. A product with this profile would enable patients to conveniently and rapidly self-administer a reliable and accurate dose of epinephrine during an anaphylactic reaction, which we

believe would result in greater patient compliance. We believe AQST-108 has the potential to reduce the treatment burden currently associated with intramuscular injections and may lower costs to the healthcare system associated with anaphylaxis, such as hospitalizations due to inaccurate or untimely dosing.

Clinical Development

We have conducted proof-of-concept studies to demonstrate our ability to deliver epinephrine via a non-invasive sublingual film. We evaluated AQST-108 in two dose escalation studies, each with six patients, in which there were no severe adverse events. In addition, we completed a Phase 1 near-term 3-way crossover study in healthy male subjects comparing epinephrine sublingual film to EpiPen intramuscular injection.

Based on the results of the Phase 1 study, we are optimizing the formulation of AQST-108. We are currently testing our new formulation in preclinical studies and expect to initiate a second Phase 1 study with the new formulation in the second quarter of 2018. Upon the completion of our second Phase 1 study, we plan on requesting a pre-IND meeting with the FDA to discuss our clinical development program.

AQST-305 (Octreotide)

Product Overview

AQST-305 is a sublingual film formulation of octreotide, an 8 amino acid peptide that has a similar pharmacological profile to natural somatostatin, for the treatment of acromegaly. We initiated a development program to demonstrate human proof-of-concept in December 2017 and expect to dose the first patient in the middle of 2018.

Limitations of Current Therapies

Acromegaly is a hormone disorder that results from the overproduction of growth hormone in middle-aged adults. The condition is typically caused by a benign tumor present in the pituitary gland that excretes excessive amounts of growth hormone and leads to exaggerated bone growth over time.

First-line treatment of acromegaly usually involves surgery to remove the tumor. Some patients are not eligible for surgery depending on the placement and size of the tumor, and in some cases, surgery does not completely remove the tumor, leading to persistently elevated growth hormone levels. The standard of care for post-surgery patients includes the chronic use of somatostatin analogues to lower production or block the action of growth hormones. The somatostatin analogues currently on the market, octreotide and lanreotide, are administered by deep subcutaneous or intramuscular injections once a month, which are invasive and painful and can represent a treatment burden for patients. We believe there is a market opportunity for a non-injectable, easier to administer product that delivers a reliable and consistent dose of octreotide.

Our Solution

We have designed AQST-305 for twice daily administration, which we believe will reduce the burden of monthly depot intramuscular injections and address the potential loss of efficacy over the treatment life cycle with currently marketed products. AQST-305 can be administered by the patient, rather than having to receive monthly injections in a physician's office. Additionally, because AQST-305 is administered twice-daily, patients will receive a consistent dose of octreotide and will not need to be concerned with the potential loss of efficacy that may otherwise result when receiving only a monthly dosage administered via injection. We believe AQST-305 will reduce the burden for patients who are looking for a non-invasive, pain-free, easier to administer product.

Clinical Development

We have conducted five preclinical studies in animal models to date, which have demonstrated initial positive results compared to Sandostatin.

We initiated a development program to demonstrate human proof-of-concept in December 2017 and expect to dose the first patient in the middle of 2018. Upon the completion of the proof-of-concept study, we plan to conduct formulation optimization work and progress to a Phase 1 study.

Partnered Products and Product Candidates

Suboxone (buprenorphine and naloxone)

Suboxone is a sublingual film formulation of buprenorphine and naloxone. Buprenorphine and naloxone are opioid antagonists that, when combined, are effective for treating opioid addiction. Suboxone reduces the potential for abuse and improves safety, clinical differentiation, dissolution, taste and texture for patients suffering from opioid addiction. According to the American Society of Addiction Medicine, drug overdose is the leading cause of accidental death in the United States, with opioid addiction driving this epidemic. Opioid dependence is estimated to affect more than two million people in the United States. Patients overcoming opioid addiction can experience painful withdrawal symptoms, which can be mitigated with the use of opioid antagonists.

Suboxone Sublingual Film was launched in partnership with Indivior in 2010 to treat opioid dependence pursuant to a commercial agreement. Indivior has an exclusive worldwide license to this product. Suboxone Sublingual Film is the market leader for buprenorphine based opioid abuse disorder treatment, capturing approximately 60% of total prescriptions in 2017, despite generic competitors. In the last four years, over 1.2 billion doses have been delivered to patients. We are the sole and exclusive manufacturer of Suboxone Sublingual Film worldwide for Indivior. See “Material Agreements – Commercial Exploitation Agreement with Indivior.”

Zuplenz (ondansetron)

Zuplenz is an oral soluble film formulation of ondansetron, a 5-HT_3 antagonist approved for the treatment of nausea and vomiting associated with chemotherapy and post-operative recovery. Ondansetron is available as intravenous injections, intramuscular injections, orally dissolving tablets, oral solution, tablets, and film. Generic and branded products are available, with the branded product marketed as Zofran by GlaxoSmithKline. According to IQVIA, ondansetron generated 25 million prescriptions and sales of $127 million in the United States in 2017. We licensed commercial rights for Zuplenz to Midatech Pharma in the United States, Canada, and China. Midatech launched Zuplenz in the United States in 2015. We are the sole and exclusive manufacturer of Zuplenz for Midatech.

APL-130277 (apomorphine)

APL-130277 is a sublingual film using apomorphine, a dopamine agonist indicated as an intermittent therapy to overcome episodic off periods in Parkinson’s disease. Parkinson’s disease affects approximately 500,000 patients in the United States. APL-130277 is designed to address an unmet need in patients who suffer from dysphagia. We licensed intellectual property for PharmFilm technology associated with APL-130277 to Cynapsus Therapeutics, which was acquired by Sunovion. Sunovion, our partner and sponsor of APL-130277, submitted an NDA to the FDA on March 29, 2018. If approved, we will earn a royalty and other milestone payments based on worldwide sales of APL-130277. See “Material Agreements – License Agreement with Sunovion Pharmaceuticals, Inc.”

AQST-119 (tadalafil)

AQST-119 is an oral soluble film formulation of tadalafil, a vasodilator that is used to treat erectile dysfunction, or ED. ED affects men primarily between the ages of 40 and 70, with approximately 10% having severe or complete ED, and 25% having moderate or intermittent erectile difficulties. AQST-119 is designed to provide patients a discreet product with increased ease of use. We submitted an NDA with the FDA in November 2016 and expect approval in 2018. We are currently seeking a commercialization partner for AQST-119.

AQST-306 (edaravone)

Additionally, we are developing AQST-306, a film formulation of edaravone in partnership with Mitsubishi Tanabe Pharma America, Inc. Edaravone is a treatment for ALS currently marketed in injectable form as Radicava.

Commercialization Strategy

We plan to focus our commercial strategy for our proprietary CNS product portfolio on building awareness through healthcare provider education, with a particular focus on neurologists and their treatment teams, as well as patient caregivers.

We have built a commercial team with significant experience earned from multiple product launches prior to joining our company, including several in the CNS space. We intend to continue adding relevant experience in sales leadership, regulatory and medical affairs, marketing, and payor and market access management to supplement our capabilities in these areas. Based on the number of treatment specialists, target patients and overlap of our initial CNS product candidates, we believe that we will be able to leverage a focused sales force effectively across these areas. We plan to hire up to 50 dedicated sales representatives in anticipation of multiple product launches through 2019. With a prescribing physician overlap between Libervant and Sympazan of greater than 80%, we estimate that with a dedicated sales team of this size can cover approximately 85% of the target patient population. The launch and marketing of our products will be focused in the United States, with any ex-U.S. commercialization efforts likely out-licensed to other companies.

Assuming FDA approval, we expect to launch Sympazan in late 2018, followed by Libervant in early 2019. In anticipation of our upcoming product launches, we will publish key data, engage a broader array of key opinion leaders, or KOLs, and large practices and continue to develop our body of clinical evidence. Additionally, we intend to utilize KOLs' knowledge through advisory boards to develop best practices and appropriate areas for use, as well as educational materials for peer physicians.

We intend to similarly develop commercialization strategies for AQST-305 and AQST-108 in advance of their respective NDA submissions, including a combination of company and partnered resources.

Manufacturing and Product Supply

We operate two redundant manufacturing and primary packaging facilities located in Portage, Indiana, where we currently manufacture our partnered products, Suboxone and Zuplenz, on a sole and exclusive basis. These facilities have a combined capacity to accommodate the production of our two marketed products and both our near-term and long-term pipeline of proprietary and partnered products, without any need for additional infrastructure. We have produced over 1.2 billion doses in the last four years. As a company, our research and development laboratories are registered with the DEA, for Schedule II-V drugs.

We do not produce API for any of our products and obtain such API from a number of different sources. The API used in Suboxone is obtained directly from Indivior. We intend to outsource secondary packaging and third-party logistics for our proprietary products.

We are subject to various regulatory requirements, such as the regulations of the FDA, the DEA, and the Therapeutics Goods Administration, or TGA. We are required to adhere to cGMP. This standard requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures throughout the entire manufacturing process. Our facilities have undergone inspections by the FDA, DEA, TGA, and several quality assurance inspections by pharmaceutical companies for cGMP compliance. In each case, the facilities have passed inspection and are subject to periodic re-inspection.

We purchase our raw materials from qualified, approved vendors both domestically and internationally. For certain components of our products, we have a single source supplier. We typically source raw materials from the lowest cost provider whenever possible and continue to pursue a multi-supplier strategy for all of our critical raw materials. We expect that we will enter into more formal supply agreements in the future as production volumes increase and are more predictive.

Competition

We compete with pharmaceutical and biotechnology companies that develop and commercialize therapeutics for the treatment of a broad range of disease areas and indications. Additionally, we compete with companies that utilize advanced drug administration platforms, such as oral, injectable, intranasal,

transdermal patch and pulmonary delivery, to create improved therapeutics over current standards of care. This industry is highly competitive and new products and technologies evolve and come to market at a rapid pace. The companies operating in this market include multinational organizations, established biotechnology companies, single product pharmaceutical and biotechnology companies, specialty pharmaceutical companies, and generic drug companies. Many of the larger, established organizations currently have commercialization capabilities in-house, and may have partnered agreements in place with smaller companies for commercialization rights. These companies may develop new drugs to treat the indications that we target, or seek to have existing drugs approved for the treatment of the indications that we target.

We will compete with commercialized products in all markets for which we are seeking approval. For outpatient treatment of emergency breakthrough seizures, Diastat (diazepam rectal gel, Valeant Pharmaceuticals International, Inc.) remains the only currently commercialized product. Several marketed products are approved for the treatment of LGS, including two products solely indicated for LGS: Onfi (clobazam, Lundbeck A/S) and Banzel (rufinamide, Eisai Co.). For ALS, generic riluzole tablets are considered the standard of care. Radicava (edaravone, Mitsubishi Tanabe Pharma Corporation), which launched in the United States in 2017, is also expected to be used as part of a comprehensive treatment plan that may also include riluzole. Commercialized products for anaphylaxis include epinephrine autoinjectors such as EpiPen (Mylan Inc.), among others. In acromegaly, marketed products include short- and long-acting somatostatin analogues, such as Sandostatin (octreotide acetate, Novartis AG), as well as the growth hormone receptor antagonist Somavert (pegvisomant, Pfizer Inc.).

There are also several product candidates undergoing clinical trials that, if approved, would compete in the markets for which we are seeking approval for our product candidates. For breakthrough seizure management, in addition to the oral delivery of benzodiazepines, intranasal and inhalable benzodiazepine formulations are also being developed. The leading benzodiazepines in development with alternative delivery forms are: Neurelis, Inc.'s intranasal diazepam currently in Phase 3 development; Xeris Pharmaceuticals, Inc.'s diazepam, an injectable form with the potential to be delivered with a pen or pump, currently in Phase 1 development; Proximagen Ltd.'s intranasal midazolam currently in Phase 3 development; and Engage Therapeutics, Inc.'s inhaled alprazolam currently in Phase 2 development. Two products are anticipated to launch in LGS in the near-term, which may be used in conjunction with the standard of care: GW Pharmaceuticals plc's Epidiolex and Eisai Co, Ltd.'s Fycompa. Two additional product candidates, Zogenix Inc.'s ZX008, currently in Phase 3 development, and Ovid Therapeutics Inc.'s TAK-935, currently in Phase 1/2 development, are oral products that may become part of the treatment paradigm for LGS patients. For anaphylaxis, INSYS Therapeutics, Inc. is developing an epinephrine intranasal spray, and announced the initiation of a Phase 1 proof-of-concept study in December 2017.

Material Agreements

Commercial Exploitation Agreement with Indivior

In August 2008, we entered into a Commercial Exploitation Agreement with Reckitt Benckiser Pharmaceuticals, Inc., or the Indivior License Agreement. Reckitt Benckiser Pharmaceuticals, Inc. later succeeded to in interest by Indivior, Inc., or Indivior. Pursuant to the Indivior License Agreement, we have agreed to manufacture and supply Indivior's requirements of Suboxone both inside and outside the United States on an exclusive basis.

Under the terms of the Indivior License Agreement, we are required to manufacture Suboxone in accordance with cGMP standards and according to the specifications and processes set forth in the related quality agreements we entered into with Indivior. Additionally, we are required to obtain API for the manufacture of Suboxone directly from Indivior. The Indivior License Agreement specifies a minimum annual threshold quantity of Suboxone that we are obligated to fill and requires Indivior to provide us with a forecast of its requirements at various specified times throughout the year.

The Indivior License Agreement provides for payment by Indivior of a purchase price per unit that is subject to adjustment based on our ability to satisfy minimum product thresholds. Additionally, in the event Indivior purchases certain large quantities of Suboxone during a specified period, Indivior will be entitled to rebates on its purchases.

In addition to the purchase price for the Suboxone supplied, Indivior is required to make certain single digit percentage royalty payments tied to net sales value (as provided for in the Indivior License Agreement) in each of the United States and in the rest of the world subject to annual maximum amounts. In the event that Indivior has paid us a specified aggregate royalty amount in royalties on Suboxone sold in the United States, then it will be required to prepay to us, an additional agreed payment amount, after which all obligations of Indivior to pay royalties on Suboxone sold in the United States will terminate. Except as set forth in the prior sentence, Indivior's royalty obligations to us continue in the United States and the rest of the world until the expiration of all of the patents (either in the United States or other territories) or upon written notice by Indivior subject to Indivior being required to pay us a final royalty payout. Indivior exercised its right to buy out its future royalty obligations in the United States in 2012. Indivior remains obligated to pay royalties for all sales outside the United States.

The Indivior License Agreement contains customary contractual termination provisions for breach or in the event of bankruptcy or corporate dissolution, the intellectual property surrounding Suboxone is found to be invalid, or either party commits a material breach of the Indivior License Agreement. Additionally, Indivior may terminate if the FDA or other applicable regulatory authority declares our manufacturing site to no longer be suitable for the manufacture of Suboxone or Suboxone is no longer suitable to be manufactured due to health or safety reasons. The initial term of the Indivior License Agreement was seven years from the commencement date. Thereafter, the Indivior License Agreement automatically renews for successive one year periods, unless Indivior provides us with written notice of its intent not to renew at least one year prior to the expiration of the initial or renewal term.

Supplemental Agreement with Indivior

On September 24, 2017, we entered into an agreement with Indivior, or the Indivior Supplemental Agreement, to clarify the scope of the relationship between the parties. Under the Indivior Supplemental Agreement, we are entitled to receive certain payments from Indivior commencing on the date of the agreement through January 1, 2023. To date we have received an aggregate of $26 million from Indivior under the Indivior Supplemental Agreement. In addition to amounts received, we may receive up to an additional $49 million, consisting of a royalty equal to a low single digit percentage of net revenue earned by Indivior on Suboxone sales and performance-based milestone payments, with the aggregate payment amounts under the Indivior Supplemental Agreement capped at $75 million.

All payments made by Indivior to us pursuant to the Indivior Supplemental Agreement are in addition to, and not in place of, any amounts owed by Indivior to us pursuant to the Indivior License Agreement. Indivior's payment obligations under the Indivior Supplemental Agreement are subject to certain factors affecting the market for Suboxone and may terminate prior to January 1, 2023 in the event certain contingencies relating to such market occur.

License Agreement with Sunovion Pharmaceuticals, Inc.

In April 2016, we entered into a license agreement with Cynapsus Therapeutics Inc. (which was later succeeded to in interest by Sunovion), or the Sunovion License Agreement, pursuant to which we granted Sunovion an exclusive, worldwide license (with the right to sub-license) to certain intellectual property, including existing and future patents and patent applications, covering all oral films containing APL-130277 (apomorphine) for the treatment of off episodes in Parkinson's disease patients, as well as two other fields. Sunovion, our partner and sponsor of APL-130277, submitted an NDA to the FDA on March 29, 2018.

In consideration for the rights granted to Sunovion under the Sunovion License Agreement, we received an upfront payment of $5 million. We are also entitled to receive pursuant to the Sunovion License Agreement (i) an aggregate of $13 million in connection with specified regulatory and development milestones in the United States and Europe, which are due and payable on or before December 1, 2018 (the "Initial Milestone Payments") $9 million of which has been received to date, (ii) certain one-time milestone payments related to product availability and regulatory approval in the United States and Europe, (iii) certain one-time milestone payments based on the achievement of specific annual net sales thresholds of APL-130277, and (iv) ongoing mid-single digit percentage royalty payments related to the net sales of APL-130277 (subject to reduction to low-single digit percentage

royalty payments in certain circumstances), subject to certain minimum payments. With the exception of the Initial Milestone Payments, there can be no guarantee that any such milestones will in fact be met or payable.

The Sunovion License Agreement will continue until terminated by us or Sunovion in accordance with the termination provisions of the Sunovion License Agreement.

As more fully described in the Sunovion License Agreement, we may terminate the Sunovion License Agreement if (i) Sunovion fails to make any payments required under the Sunovion License Agreement when due and after receiving certain notices from us; (ii) Sunovion fails to commercialize APL-130277 in at least one Major Market (as defined in the Sunovion License Agreement) by January 1, 2020; (iii) Sunovion pays us not more than the minimum royalty payment due for any 30 consecutive months from the date of first commercial sale; (iv) Sunovion fails a primary endpoint of its Phase 3 studies (CTH-300 and CTH-301) and either fails to start another Phase 3 study within six months after such failed primary endpoint, or fails a primary endpoint of any subsequent Phase 3 study; (v) Sunovion publicly challenges the validity or enforceability of the Licensed Patents (as defined in the Agreement); or (vi) no further royalty payments are due and payable to us.

As more fully described in the Sunovion License Agreement, Sunovion generally may terminate the Sunovion License Agreement if (i) we fail to use commercially reasonable efforts to defend the Licensed Patents in response to a Patent Infringement Claim (as defined in the Sunovion License Agreement); (ii) we are in material breach of the Sunovion License Agreement, which breach is not remedied after receiving notice thereof; (iii) prior to commercialization of APL-130277, upon certain notice to us, if Sunovion has abandoned further development of APL-130277; or (iv) at any time after December 31, 2024, for any reason upon certain notice to us. Sunovion may also terminate the Sunovion License Agreement if it can establish that a Material Decline (as defined in the Agreement) has occurred in a jurisdiction as a result of us licensing to a third party any Licensed Patents to develop or commercialize apomorphine either alone or in combination with another active agent, for any human use, solely with respect to such jurisdiction(s) that have suffered a Material Decline, upon certain notice to us.

Additionally, either party may terminate the Sunovion License Agreement (i) in connection with certain bankruptcy events; or (ii) in connection with certain material misrepresentations; breach of representations, warranties or covenants; or breach of exclusivity or confidentiality provisions, as set forth in the Sunovion License Agreement. The Sunovion License Agreement also contains, without limitation, customary representations, warranties and covenants of the parties, as well as provisions relating to confidentiality, indemnification and other matters.

Agreement to Terminate CLA with KemPharm

In March 2012, we entered into an agreement with KemPharm, Inc. or KemPharm, to terminate a Collaboration and License Agreement entered into in April 2011, or the KemPharm Termination Agreement. Pursuant to the KemPharm Termination Agreement, KemPharm made a one-time payment to us of $11 million upon the closing of a transaction with Shire LLC related to KemPharm's product candidate KP106. We also have the right to receive payments in the mid-single to low double-digit percentages of any "value" (as such term is defined in the KemPharm Termination Agreement) generated by KP415, and any product candidates arising therefrom, including, but not limited to royalty payments on any license of KP415, the sale of KP415 to a third party, the commercialization of KP415 and the portion of any consideration that is attributable to the value of KP415 and paid to KemPharm or its stockholders in a change of control transaction. KP415 is a new molecular entity prodrug of methylphenidate, which is being developed by KemPharm for the treatment of ADHD. KP415 is designed to be a controlled release, abuse-deterrent methylphenidate product.

KemPharm has no obligation pursuant to the KemPharm Termination Agreement to develop or commercialize KP415. The KemPharm Termination Agreement has customary cross-indemnification provisions and KemPharm's payment obligations to us with respect to KP415 continue indefinitely until all payments due under the KemPharm Termination Agreement in respect of "value" received on KP415 are made to us. KP415 recently completed Phase 2 studies.

Intellectual Property

We currently seek, and intend to continue seeking, patent protection whenever commercially reasonable for any patentable aspects of our product candidates and related technology or any new products or product candidates we acquire in the future. Where our intellectual property is not protected by patents, we may seek to protect it through other means, including maintenance of trade secrets and careful protection of our proprietary information.

In addition, we intend to seek orphan drug exclusivity in jurisdictions in which it is available. A prerequisite to orphan drug exclusivity in the United States and in the European Union is orphan drug designation. An orphan drug designation may be granted where a drug is developed specifically to treat a rare or uncommon medical condition. If a product which has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug for the same indication, except in certain very limited circumstances, for a period of seven years in the United States and 10 years in the European Union. Orphan drug exclusivity does not prevent competitors from developing or marketing different drugs for the indication protected by exclusivity, or the same drug for a different indication.

Patents

Our patent portfolio currently comprises at least 200 issued patents worldwide, of which at least 40 are U.S. patents, and more than 75 pending patent applications worldwide. These issued patents and pending patent applications provide both process of making and composition of matter protection for our PharmFilm technology and products and product candidates, including Suboxone and our PharmFilm dosaqe formulations of, tadalafil, diazepam, clobazam, riluzole, epinephrine and octreotide. These patents and, if issued as patents, pending patent applications will expire between 2022 and 2037. The pending patent applications filed in 2017 will provide composition of matter and process of making protection for our PharmFilm dosage formulations of diazepam, epinephrine and octreotide, and if issued as patents, will expire by 2037. The projected expiration dates exclude any patent term adjustment or patent term extension.

PharmFilm – Our Oral Film Technology

Our PharmFilm platform technology is covered by at least 8 patent families. These patent families provide process, composition of matter protection for our PharmFilm platform technology, and comprise at least 47 issued patents worldwide, of which at least 18 are U.S. patents, and related pending patent applications worldwide. The patents and pending patent applications, if issued as patents, will expire between 2022 and 2037, excluding any patent term adjustment or patent term extension.

The PharmFilm platform technology patents also generically and specifically protect the technology utilized in the products and product candidates in our CNS programs, our Complex Molecule Programs, as well as our Partner Programs. For example, encompassed within our platform technology patents is specific coverage directed to PharmFilm dosage formulations of CNS molecules such as diazepam. Also encompassed within our platform technology is coverage for our complex molecule program which includes molecules such as epinephrine. Our platform technology patents further cover the products Suboxone and Zuplenz, as well as our PharmFilm dosaqe formulations of the molecules apomorphine and tadalafil, which are part of our partnered programs. The expiration dates for patents covering these products and product candidates, and for pending applications if issued as patents, are between 2022 and 2037, excluding any patent term adjustment or patent term extension.

We note that several of our issued patents are or have been involved in administrative proceedings, such as reexamination and inter partes review at the U.S. Patent and Trademark Office, or USPTO and opposition at the European Patent Organization, or EPO. Four of our European patents are under opposition proceedings at the appeal stage. These patents include one European patent which relates to our early process technology, and two European patents which relate to our taste-masking technology, all three of which are included in our PharmFilm platform technology. We also note that several of our issued patents are involved in litigations. For more information, please see the section titled “Business — Legal Proceedings.”

Certain of our patents and patent applications if granted, will be published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA. If any of these potential generic competitors claim that their product will not infringe our listed patents, or that such patents are invalid, then they must send notice to us once the ANDA or 505(b)(2) NDA has been accepted for filing by the FDA. We may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification, which would automatically prevent the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) NDA applicant.

The rest of our patent portfolio largely relates to patents and applications owned by us and directed to our product development portfolio and other product candidates and related compositions and/or manufacturing processes.

Trade Secrets and Other Proprietary Information

We seek to protect our proprietary information, including our trade secrets and proprietary know-how, by requiring our employees, consultants and other advisors to execute confidentiality agreements upon the commencement of their employment or engagement. These agreements generally provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not be disclosed to third parties except in specific circumstances. In the case of our employees, the agreements also typically provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed during employment shall be our exclusive property to the extent permitted by law. Where appropriate, agreements we obtain with our consultants also typically contain similar assignment of invention provisions. Further, we generally require confidentiality agreements from business partners and other third parties that receive our confidential information. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

Trademarks

We also rely on trademarks and trade designs to develop and maintain our competitive position. Our trademarks or registered trademarks are filed of ours in the United States and other select geographical areas.

Regulatory

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or FDCA and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable FDA or other requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending applications, clinical holds, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, withdrawal of product from the market, injunctions, fines, civil penalties and criminal prosecution.

FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. The process required by the FDA before a new drug may be marketed in the United States generally involves:

- completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA’s current good laboratory practice, or GLP, regulations;
- submission to the FDA of an Investigational New Drug, or IND, application for human clinical testing which must become effective before human clinical trials may begin in the United States;

- approval by an independent institutional review board, or IRB, at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each intended use;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with the FDA's cGMP regulations to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of a potential review by an FDA advisory committee, if applicable; and
- FDA review and approval of the NDA.

The preclinical and clinical testing and approval process takes many years and the actual time required to obtain approval, if any, may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLPs. The results of preclinical testing are submitted to the FDA as part of an IND application along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND application is submitted.

The IND application automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to one or more proposed clinical trials and places the clinical trial on a clinical hold, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. A separate submission to an existing IND application must also be made for each successive clinical trial conducted during product development. Further, an independent IRB, covering each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and informed consent information for subjects before the trial commences at that site and it must monitor the study until completed. The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk or for failure to comply with the IRB's requirements, or may impose other conditions. Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Sponsors of clinical trials generally must register and report, at the NIH-maintained website ClinicalTrials.gov, key parameters of certain clinical trials. For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

Phase 1: In Phase 1, through the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness.

Phase 2: Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks.

Phase 3: Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to

provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. Under federal law, the submission of most NDAs is subject to a substantial application user fee, and applicant under an approved NDA is also subject to an annual program fee for each prescription drug product, which beginning in Fiscal Year 2018 replaced the product and establishment fees.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under PDUFA the FDA has agreed to certain performance goals in the review of NDAs through a two-tiered classification system, Standard Review and Priority Review. Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. The FDA endeavors to review applications subject to Standard Review within ten to twelve months, whereas the FDA's goal is to review Priority Review applications within six to eight months.

The FDA may refer applications for proprietary drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless it determines that the manufacturing process and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the NDA and may require substantial additional testing, or information, in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA may ultimately decide that an application does not satisfy the regulatory criteria for approval. If, or when, the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

As a condition of NDA approval, the FDA may require a REMS to help ensure that the benefits of the drug outweigh the potential risks. If the FDA determines a REMS is necessary during review of the application, the drug sponsor must agree to the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other elements to assure safe use, such as special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. In addition, the REMS must include a timetable to periodically assess whether the REMS plan is effective. The requirement for a REMS can materially affect the potential market and profitability of a drug.

Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms.

Further changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the similar procedures in reviewing NDA supplements as it does in reviewing NDAs.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to drug listing and registration, recordkeeping, periodic reporting, product sampling and distribution, adverse event reporting and advertising, marketing and promotion, including standards and regulations for direct to consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. While physicians may prescribe for off-label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, quality-control, drug manufacturing, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced and announced inspections by the FDA and these state agencies, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered. The FDA may also impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug’s benefits outweigh its risks. In addition, regulatory authorities may take other enforcement action, including, among other things, warning letters, the seizure of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, refusal to approve pending applications or supplements to approved applications, civil penalties and criminal prosecution.

The FDA may require post-approval studies and clinical trials if the FDA finds that scientific data, including information regarding related drugs, deem it appropriate. The purpose of such studies would be to assess a known serious risk or signals of serious risk related to the drug or to identify an unexpected serious risk when available data indicate the potential for a serious risk. The FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of a drug.

In addition, any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, or PDMA, a part of the FDCA. In addition, Title II of the Federal Drug Quality and Security Act of 2013, known as the Drug Supply Chain Security Act or the DSCSA, has imposed new “track and trace” requirements on the distribution of prescription drug products by manufacturers, distributors, and other entities in the drug supply chain. These requirements are being

phased in over a ten-year period. The DSCSA ultimately will require product identifiers (*i.e.*, serialization) on prescription drug products in order to establish an electronic interoperable prescription product system to identify and trace certain prescription drugs distributed in the United States. The DSCSA replaced the prior drug "pedigree" requirements under the PDMA, and preempts existing state drug pedigree laws and regulations. The DSCSA also establishes new requirements for the licensing of wholesale distributors and third-party logistic providers. These licensing requirements preempt states from imposing licensing requirements that are inconsistent with, less stringent than, directly related to, or otherwise encompassed by standards established by FDA pursuant to the DSCSA. Until FDA promulgates regulations to address the DSCSA's new national licensing standard, current state licensing requirements typically remain in effect.

The Hatch-Waxman Amendments

ANDA Approval Process

The Hatch-Waxman Amendments established abbreviated FDA approval procedures for drugs that are shown to be equivalent to drugs previously approved by the FDA through its NDA process. Approval to market and distribute these drugs is obtained by submitting an ANDA to the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug. In certain situations, an applicant may obtain ANDA approval of a generic product with a strength or dosage form that differs from a referenced innovator drug pursuant to the filing and approval of an ANDA Suitability Petition. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if the FDA determines that it is not equivalent to the referenced innovator drug, if it is intended for a different use, or if it is not subject to an approved Suitability Petition. However, such a product might be approved under an NDA, with supportive data from clinical trials.

505(b)(2) NDAs

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant. If the 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved branded reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the branded reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Orange Book Listing

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents with claims that cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (i) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (ii) such patent has expired; (iii) the date on which such patent expires; or (iv) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the

certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a “section viii” statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the reference drug NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below.

Non-Patent Exclusivity

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent related exclusivity, during which the FDA cannot review, or in some cases, approve an ANDA or 505(b)(2) application that relies on the listed drug. For example, a company may obtain five years of non-patent exclusivity upon NDA approval of a NCE which is a drug that contains an active moiety that has not been approved by FDA in any other NDA. An “active moiety” is defined as the molecule or ion responsible for the drug substance’s physiological or pharmacologic action. During the five year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA for the same active moiety and that relies on the FDA’s findings regarding that drug, except that FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification.

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation of a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the exclusivity period.

Orphan Drug Designation and Exclusivity

The Orphan Drug Act provides incentives for the development of products intended to treat rare diseases or conditions. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. If a sponsor demonstrates that a drug is intended to treat rare diseases or conditions, the FDA will grant orphan designation for that product for the orphan disease indication. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation, however, does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Orphan drug designation provides manufacturers with research grants, tax credits and eligibility for orphan drug exclusivity. If a product that has orphan drug designation subsequently receives the first FDA approval of the active moiety for that disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which for seven years prohibits the FDA from approving another product with the same active ingredient for the same indication, except in limited circumstances. If a drug designated as an orphan product receives marketing approval for an indication broader than the orphan indication for which it received the designation, it will not be entitled to orphan drug exclusivity. Orphan exclusivity will not bar approval of another product under certain circumstances, including if a subsequent

product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. Further, the FDA may approve more than one product for the same orphan indication or disease as long as the products contain different active ingredients. Moreover, competitors may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. As a result, even if one of our product candidates receives orphan exclusivity, we may still be subject to competition. Orphan exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or if our product candidate is determined to be contained within the competitor's product for the same indication or disease.

Anti-Kickback and False Claims Laws and Other Regulatory Matters

In the United States, we are subject to complex laws and regulations pertaining to healthcare "fraud and abuse," including, but not limited to, the Federal Anti-Kickback Statute, the Federal False Claims Act, and other state and federal laws and regulations. The Federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the Federal Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid.

The Federal False Claims Act prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Although we would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been found liable under the Federal False Claims Act in connection with their off-label promotion of drugs. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $10,000 and $25,000 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the Federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. In addition, private individuals have the ability to bring actions under the Federal False Claims Act and certain states have enacted laws modeled after the Federal False Claims Act.

The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which we refer to collectively as HIPAA, also created several additional federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services.

There are also an increasing number of state laws with requirements for manufacturers and/or marketers of pharmaceutical products. Some states require the reporting of expenses relating to the marketing and promotion of drug products and the reporting of gifts and payments to individual healthcare

practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Still other states require the reporting of certain pricing information, including information pertaining to and justification of price increases, or prohibit prescription drug price gouging. In addition, states such as California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, as discussed below, a similar federal requirement requires manufacturers to track and report to the federal government certain payments made to physicians and teaching hospitals made in the previous calendar year. These laws may affect our sales, marketing and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state, and soon federal, authorities.

The Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to certain payments made in the previous calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

In addition, HIPAA, and its implementing regulations impose certain obligations on entities subject to the law, such as health plans and most healthcare providers, and their business associates who provide certain services involving the use or disclosure of HIPAA protected health information on their behalf, with respect to the privacy and security of such protected health information. Further, most states have enacted laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances, such as specific disease states.

Compliance with such laws and regulations will require substantial resources. Because of the breadth of these various fraud and abuse laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have material adverse effects on our business, financial condition and results of operations. In the event governmental authorities conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, they may impose sanctions under these laws, which are potentially significant and may include civil monetary penalties, damages, exclusion of an entity or individual from participation in government health care programs, criminal fines and individual imprisonment, additional reporting requirements if we become subject to a corporate integrity agreement or other settlement to resolve allegations of violations of these laws, as well as the potential curtailment or restructuring of our operations. Further, we may be subject to contractual damages and reputational harm as result of such non-compliance. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity.

International Regulation

In addition to regulations in the United States, we are and will be subject to a variety of foreign regulations regarding development, approval, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional review periods, and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing, among other things, the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

In the European Union, or EU, we may seek marketing authorization under either the centralized authorization procedure or national authorization procedures.

Centralized procedure. The European Medicines Agency, or EMA, implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the EU. This procedure results in a single marketing authorization issued by the European Commission following a favorable opinion by the EMA that is valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

National authorization procedures. There are also two other possible routes to authorize medicinal products in several European Union countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure: the decentralized procedure and the mutual recognition procedure. Under the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country for medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure. Under the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following a national authorization, the applicant may seek further marketing authorizations from other EU countries under a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In the EU, medicinal products designated as orphan products benefit from financial incentives such as reductions in marketing authorization application fees or fee waivers and 10 years of marketing exclusivity following medicinal product approval. For a medicinal product to qualify as orphan: (i) it must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating; (ii) the prevalence of the condition in the EU must not be more than five in 10,000 or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development; and (iii) no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorized, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

United States Healthcare Reform

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the PPACA, substantially changes the way healthcare is financed by both governmental and private insurers and significantly impacts the pharmaceutical industry. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program, or commonly known as the donut hole, rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicaid Drug Rebate program, expansion of the Public Health Service's 340B drug pricing discount program, or 340B program, fraud and abuse, and enforcement. These changes impact existing government healthcare programs and are resulting in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Some states have elected not to expand their Medicaid programs to individuals with an income of up to 133% of the federal poverty level, as is permitted under the PPACA. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales of products for which we receive regulatory approval, business and financial condition. Where

new patients receive insurance coverage under any of the new Medicaid options made available through the PPACA, the possibility exists that manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues.

Some of the provisions of the PPACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the PPACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the PPACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the Medicare Part D donut hole. Congress will likely consider other legislation to replace elements of the PPACA.

Moreover, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, then President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation’s automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. Further, in January 2013, then President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In addition, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration’s budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the PPACA, as currently enacted or as it may be amended or replaced in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of products for which we receive regulatory approval or to successfully commercialize our product candidates, if approved.

Coverage and Reimbursement

Payor coverage uncertainty exists for all pharmaceutical products that are launched. This uncertainty exists as to the coverage of any products for which we may obtain regulatory approval. Sales of any of our products and product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government healthcare programs such as Medicare and Medicaid, and private payors, such as commercial health insurers and managed care organizations. Third-party payors determine which drugs they will cover. In the United States, there is no uniform system among payors for making coverage decisions. Decisions regarding the extent of coverage for any product candidates that we develop will be made on a payor-by-payor basis. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. A decision by a payor to not cover our product candidates could reduce physician adoption of our product candidates, once approved, and have a material adverse effect on our sales, results of operations and financial condition.

In order to secure coverage for our products, if approved for sale, we may need to conduct pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the studies required to obtain FDA or other comparable regulatory approvals. Even if we conduct such pharmacoeconomic studies, our products and product candidates may not be considered medically necessary or cost-effective by payors.

We intend to pursue a reasonable and credible approach to the pricing of our products, in order to avoid such products being categorized as specialty products. Determination of responsible pricing will be based on the value proposition of our products, a full therapeutic category review, competitive pricing analysis and a strategic review of the payor landscape and payor dynamics. The payor type (business mix), will determine net pricing. Payor type by product (*e.g.*, Medicaid, Medicare, Commercial) will vary and therefore require varying discount levels. The Centers for Medicare and Medicaid Services, or CMS, surveys and publishes retail pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost, or NADAC, files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates.

Participation in the Medicaid Drug Rebate program would require us to pay a rebate for each unit of drug reimbursed by Medicaid. The amount of the "basic" portion of the rebate for each product is set by law as the larger of: (i) 23.1% of quarterly Average Manufacturer Price, or AMP, or (ii) the difference between quarterly AMP and the quarterly best price available from us to any commercial or non-governmental customer, or Best Price. AMP must be reported on a monthly and quarterly basis and Best Price is reported on a quarterly basis only. In addition, the rebate also includes the "additional" portion, which adjusts the overall rebate amount upward as an "inflation penalty" when the drug's latest quarter's AMP exceeds the drug's AMP from the first full quarter of sales after launch, adjusted for increases in the Consumer Price Index-Urban. The upward adjustment in the rebate amount per unit is equal to the excess amount of the current AMP over the inflation-adjusted AMP from the first full quarter of sales. The rebate amount is recomputed each quarter based on our report to CMS of current quarterly AMP and Best Price for our drug. The terms of our participation in the program would impose a requirement for us to report revisions to AMP or Best Price within a period not to exceed 12 quarters from the quarter in which the data was originally due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision. This "inflation penalty", also known as the Medicaid CPI Penalty, results from price increases in excess of the Consumer Price Index.

Federal law requires that any manufacturer that participates in the Medicaid Drug Rebate program also participate in the 340B program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B “ceiling price” for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Any changes to the definition of AMP and the Medicaid rebate amount under the PPACA or other legislation could affect our 340B ceiling price calculations and negatively impact our results of operations.

In the United States Medicare program, outpatient prescription drugs may be covered under Medicare Part D. Medicare Part D is a voluntary prescription drug benefit, through which Medicare beneficiaries may enroll in prescription drug plans offered by private entities for coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans provided for under Medicare Part C.

Coverage for covered outpatient drugs under Part D is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Although Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, they have some flexibility to establish those categories and classes and are not required to cover all of the drugs in each category or class. Medicare Part D prescription drug plans may use formularies to limit the number of drugs that will be covered in any therapeutic class and/or impose differential cost sharing or other utilization management techniques.

The availability of coverage under Medicare Part D may increase demand for products for which we receive marketing approval. However, in order for the products that we market to be included on the formularies of Part D prescription drug plans, we likely will have to offer net pricing that is lower than the prices we might otherwise obtain. Changes to Medicare Part D that give plans more freedom to limit coverage or manage utilization, and other cost reduction initiatives in the program could decrease the coverage and price that we receive for any approved products and could harm our business.

Pricing and rebate calculations, which vary across products and programs, are complex, and are often subject to interpretation by manufacturers, governmental or regulatory agencies, and the courts. Civil monetary penalties can be applied if a manufacturer is found to have knowingly submitted any false price information to the government or fails to submit the required price data on a timely basis. Such conduct also could be grounds for CMS to terminate the manufacturer's Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid. In addition, claims submitted to federally-funded healthcare programs, such as Medicare and Medicaid, for drugs priced based on incorrect pricing data provided by a manufacturer can implicate the federal Civil False Claims Act.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. The United States government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. For example, the PPACA expanded manufacturers' rebate liability under the Medicaid program from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well, increased the minimum Medicaid rebate due for most innovator drugs, and capped the total rebate amount for innovator drugs at 100% of AMP. The PPACA and subsequent legislation also changed the definition of AMP. In addition, the PPACA requires pharmaceutical manufacturers of branded prescription drugs (excluding orphan drugs) to pay a branded prescription drug fee to the federal government. Each such manufacturer pays a prorated share of the branded prescription drug fee of $4.0 billion in 2017, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. The PPACA also expanded the Public Health Service's 340B program to include additional types

of covered entities. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners, and a significant number of provisions are not yet, or have only recently become, effective. It appears likely that the PPACA will continue the pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and may also increase our regulatory burdens and operating costs.

Legislative changes to and regulatory changes under the PPACA and other healthcare statutes remain possible in the 115th United States Congress and under the Trump administration, as discussed above under the heading “United States Healthcare Reform.” In addition, there likely will continue to be proposals by legislators at both the federal and state levels, regulators, and third-party payors to contain healthcare costs. Thus, even if we obtain favorable coverage for any products for which we receive regulatory approval, less favorable coverage policies may be implemented in the future.

Additional information regarding these programs is discussed under the heading “If we are unable to achieve and maintain adequate levels of coverage and reimbursement for our products or product candidates, if approved, their commercial success may be severely hindered” in the “Risk Factors” section of this prospectus.

Other Regulation

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA and other government agencies have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

Employees

As of December 31, 2017, we had 172 employees (not including contract and temporary workers). Of these employees, six hold Ph.D. degrees. All of our employees are full-time; 19 of these are directly involved in research and development, and 121 are involved in manufacturing operations.

We are subject to local labor laws and regulations with respect to our employees in those jurisdictions. These laws principally concern matters such as paid annual vacation, paid sick days, length of the workday and work week, minimum wages, pay for overtime, and insurance for workers' compensation.

Our employees are not represented by a labor union. We do not have written employment contracts with most of our employees, and it is our understanding that our relations with our employees are satisfactory.

Properties/Facilities

We lease our 8,400-square-foot current production facility (Melton) in Portage, Indiana, which houses certain research and development offices and current good manufacturing practices, or cGMP, manufacturing operations. The lease contains an option to purchase the facility at any time during the lease term along with a right of first refusal to purchase the facility. In October 2017, we extended our Melton facility lease which will expire during March 2023 under the same terms and conditions as its former lease. Our current monthly rent for this facility is $18,664.

We also lease a 73,000-square-foot facility (Ameriplex) in Portage, Indiana, to house additional packaging, R&D and other operations. As amended, this lease has a term that extends through September 30, 2022 and contains a renewal option that could extend the lease through September 30, 2026. Our monthly rent for this facility is currently $45,570.

We lease our headquarters and principal laboratory facility in Warren, New Jersey. Pursuant to various amendments in February 2011, June 2012 and May 2013, we have secured additional space to provide for the growth of its laboratory facilities and corporate and administrative requirements. The lease included five two-year renewal options, one of which was exercised in July 2016 to extend this lease through February 28, 2020. Our monthly rent for this facility is currently $23,020.

Legal Proceedings

We are involved in various claims, legal proceedings and investigations both in the United States and internationally, most of which are either immaterial or incidental to the ordinary course of our business, other than those proceedings described below. While it is not feasible to predict the outcome of such pending claims, proceedings and investigations with certainty, management is of the opinion that their ultimate resolution should not have a material adverse effect on Aquestive's financial position, cash flows, or results of operations, except where noted below.

Patent-Related Litigation

Beginning in August 2013, we were informed of ANDA filings in the United States by Watson Laboratories, Inc. (now Actavis Laboratories, Inc., or Actavis), Par Pharmaceutical, Inc., or Par, Alvogen Pine Brook, Inc., or Alvogen, Teva Pharmaceuticals USA, Inc., or Teva, Sandoz Inc., or Sandoz, and Mylan Technologies Inc. or Mylan, for the approval by the FDA of generic versions of Suboxone Sublingual Film in the United States. We filed patent infringement lawsuits against all six generic companies in the U.S. District Court for the District of Delaware. Of these, cases against two of the six generic companies have been resolved.

- *Sandoz*. By court order in August 2016, our ANDA patent litigation case against Sandoz has been dismissed without prejudice for lack of subject matter jurisdiction because Sandoz is no longer pursuing a Paragraph IV certification for its proposed generic version of Suboxone Sublingual Film, and therefore is no longer challenging the validity or infringement of our Orange Book-listed patents.
- *Mylan*. The case against Mylan was settled and the Court signed a Consent Judgment in September 2017 disposing of the entire case.

After the commencement of litigation the above-mentioned ANDA patent litigation case against Teva, Dr. Reddy's Laboratories acquired the ANDA filings for Teva's buprenorphine and naloxone sublingual film that are at issue in these trials.

Trials against Dr. Reddy's, Actavis and Par in the lawsuits involving the Orange Book and process patents occurred in November-December of 2015 and November of 2016. On June 3, 2016, the Court issued its Trial Opinion finding that the asserted claims of U.S. Patent No. 8,603,514, or the '514 patent, are valid and infringed by Watson's and Par's ANDA Products. On August 31, 2017, the Court upheld U.S. Patent No. 8,900,497, or the '497 patent, as valid but not infringed by Par's, Watson's or Dr. Reddy's proposed processes for making their ANDA Products. The Court also again upheld the validity of the '514 patent but held it was not infringed by Dr. Reddy's ANDA Products, and upheld the validity of U.S. Patent No. 8,017,150, or the '150 patent, but held that it was not infringed by Dr. Reddy's ANDA Products. All of these cases are consolidated on appeal to the Federal Circuit. Trial against Alvogen was held in September, 2017. The only issue raised at trial was whether Alvogen's ANDA Products and processes infringe the '514 and '497 patents; Alvogen did not challenge the validity of the patents. In March 2018, the Court issued a Memorandum Opinion holding that Alvogen does not infringe the '514 and '497 patents. Indivior has announced its intention to appeal the ruling. If any company is able to obtain FDA approval for its generic version of Suboxone Sublingual Film, it may be able to launch the product prior to the expiration of any or all the applicable patents protecting our Suboxone Film, which could have a material adverse effect on our business, prospects, results of operations and financial condition.

We are also seeking to enforce our patent rights in multiple cases against BioDelivery Sciences International, Inc., or BDSI. Two cases are currently pending but stayed in the U.S. District Court for the Eastern District of North Carolina:

- The first, a declaratory judgment action brought by BDSI against Indivior and Aquestive, seeks declarations of invalidity and non-infringement of U.S. Patents Nos. 7,897,080, or the '080 patent, 8,652,378, or the '378 patent, and 8,475,832, or the '832 patent. This case stayed pending *inter partes* review of the '832 patent and reexamination of the '080 patent.
- The second was filed by us and Indivior related to BDSI's infringing Bunavail product, and alleges infringement of our patent, U.S. Patent No. 8,765,167, or the '167 patent. This case was initially filed in September 2014 in the U.S. District Court for the District of New Jersey but was transferred to North Carolina. Shortly after the case was filed, BDSI filed an IPR challenging the

asserted ’167 patent. On March 24, 2016, the Patent Trial and Appeal Board, or the PTAB, issued a final written decision finding the ’167 patent was not unpatentable. This case is stayed pending the outcome and final determination of the proceedings concerning the ’167 patent, which is currently on appeal to the Federal Circuit (discussed below).

On January 13, 2017, we also sued BDSI asserting infringement of the ’167 patent by BDSI’s Belbuca product. The case was originally filed in the U.S. District Court for the District of New Jersey, and was later transferred to the U.S. District Court for the District of Delaware by agreement of the parties.

On November 28, 2016, after the PTAB issued its final written decisions finding that the ’167 patent was not unpatentable in IPR2015-00165, IPR2015-00168 and IPR2015-00169, BDSI filed a notice of appeal of those decisions to the U.S. Court of Appeals for the Federal Circuit. The case has been fully briefed and the Court heard oral arguments on February 9, 2018. As of the date of this prospectus, there have been no further updates on this matter.

In September 2017, Indivior brought suit against Alvogen for infringement of U.S. Patent No. 9,687,454, or the ’454 patent, based on the filing of an ANDA seeking approval for a generic version of Suboxone Sublingual Film, in the U.S. District Court for the District of New Jersey. In February 2018, we and Indivior amended the complaint, which added us as a plaintiff and a claim for infringement of U.S. Patent No. 9,855,221, or the ’221 patent.

Indivior brought suits against Dr. Reddy’s and Teva in September 2017, and against Par and certain affiliates in October 2017, for infringement of the ’454 patent, in the U.S. District Court for the District of New Jersey. Indivior also brought suit in September 2017 against Actavis Laboratories UT, Inc. for infringement of the ’454 patent, in the U.S. District Court for the District of Utah. On March 13, 2018, the Court granted transfer of this case to the U.S. District Court for the District of Delaware.

In February 2018, we and Indivior brought suit against Actavis, Dr. Reddy’s, Teva, and Par and certain affiliates for infringement of the ’221 patent. The suit against Actavis was filed in the U.S. District Court for the District of Utah, and the other three cases were filed in the U.S. District Court for the District of New Jersey.

Antitrust Litigation

On September 22, 2016, forty-one states and the District of Columbia, or the States, brought suit against Indivior and us in the U.S. District Court for the Eastern District of Pennsylvania, alleging violations of federal and state antitrust statutes and state unfair trade and consumer protection laws relating to Indivior’s launch of Suboxone Sublingual Film in 2010. After filing, the case was consolidated for pre-trial purposes with the *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation*, MDL No. 2445, or the Suboxone MDL, a multidistrict litigation relating to putative class actions on behalf of various private plaintiffs against Indivior relating to its launch of Suboxone Sublingual Film. While we were not named as a defendant in the original Suboxone MDL cases, the action brought by the States alleges that we participated in an antitrust conspiracy with Indivior in connection with Indivior’s launch of Suboxone Sublingual Film and engaged in related conduct in violation of federal and state antitrust law. We moved to dismiss the States’ claims conspiracy claims, and by order dated October 30, 2017, the Court denied our motion to dismiss. We filed an answer denying the States’ claims on November 20, 2017. The parties are now proceeding with fact discovery, which is currently scheduled to be completed by July 27, 2018.

Products Liability Litigation

On December 27, 2016, we were named as a co-defendant in a product liability suit brought by Laurence and Michelle Allen, as Co-Administrators of the Estate of John Bradley Allen, in the U.S. District Court for the Northern District of New York. The suit, which also named Indivior Inc. and Indivior PLC as defendants, asserts causes of action for negligence, strict liability, and failure to warn against the defendants in connection with the manufacture and sale of Suboxone Sublingual Film. Plaintiffs allege that John Bradley Allen’s use of Suboxone Sublingual Film was a substantial contributing cause of his mental anguish and death, and seek $100 million in damages. All defendants moved to dismiss the complaint on April 10, 2017, and those motions were fully briefed on May 18, 2017. The motions to dismiss remain pending.

MANAGEMENT

Executive Officers, Directors and Key Employees

The following table sets forth certain information regarding our executive officers, directors and key employees as of December 31, 2017:

Name	Age	Position(s)
Executive Officers and Key Employees		
Keith J. Kendall	60	President, Chief Executive Officer and Director
Daniel Barber	42	Corporate, Business & Product Development
Peter Boyd	52	Operations and Management
Ken Marshall	58	Commercial
John T. Maxwell	53	Chief Financial Officer
A. Mark Schobel	62	Chief Innovation and Technology Officer and Director
Theresa Wood	55	Human Resources
Non-Employee Directors		
Douglas Bratton(2)(3)	58	Chairman of the Board of Directors
Gregory Brown, M.D.(1)(3)	64	Director
John Cochran(2)(3)	52	Director
Santo Costa(1)(2)	72	Director
James S. Scibetta(1)	53	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

Executive Officers and Key Employees

Keith J. Kendall has served as our President and Chief Executive Officer since November 2014, after having served as our President and Chief Operating Officer since November 2011, and has served on our board of directors since November 2014. Mr. Kendall also served as our Executive Vice President and Chief Financial Officer beginning in 2006. Mr. Kendall served on the board of directors of Midatech, Pharma Plc (Nasdaq: MTP), from January 2010 to December 2014. From 1999 to 2006, Mr. Kendall served as the Vice President and Managing Director of the Americas for Hewlett Packard Financial Services. Mr. Kendall held a number of positions with AT&T Capital Corporation, including President of AT&T Credit Corporation and NCR Credit Corporation, from 1985 to 1998. Mr. Kendall is a certified management accountant, and holds a BS from St. John's University and an MBA from Pace University. Our board of directors believes that Mr. Kendall's perspective and experience as our President and Chief Executive Officer, as well as his depth of operating and senior management experience in our industry, qualifies him to serve on our board of directors.

Daniel Barber joined our team in July 2007 and has led our Corporate, Business and Product Development functions since April 2014. Prior to joining our team, Mr. Barber held various positions with Quest Diagnostics in its corporate planning and international divisions. In 2010, Mr. Barber had executive oversight of our launch activities for our first two FDA approved products. Beginning in 2013, Mr. Barber helped lead our effort to develop an internal pipeline of proprietary assets. Since that time, he has had executive responsibility for our pipeline and partnership activities. Mr. Barber received his BA degree from State University of New York at Geneseo and an MBA from Seton Hall University.

Peter Boyd joined our company in August 2013 and has led our Operations and Management function since April 2014. Prior to his current position, Mr. Boyd was our Vice President of Business Process at Aquestive. Prior to joining us, Mr. Boyd served as Senior Director of Operations for the Americas and APJ Regions, at Hewlett-Packard Company. Throughout his 15-year career at the Hewlett-Packard Company, Mr. Boyd held a variety of positons in business process improvement and in

operations. Mr. Boyd received a BA in History from Wittenberg University and an MBA in Finance from Seton Hall University. Mr. Boyd also received an MS in Management and Urban Policy Analysis from the New School University.

Ken Marshall joined our company in January 2018 as the head of our commercial function. Prior to that, Mr. Marshall served as U.S. President and Global Chief Marketing Officer for Aerocrine Inc. In that role, he developed the global marketing strategy and led all aspects of the U.S. business. Between 2008 and 2011, Mr. Marshall served as Vice President of Sales and Marketing for Ikaria, Inc., a drug and device company focused on critical care. Mr. Marshall also spent 17 years with GlaxoSmithKline and held several senior positions including Vice President of Marketing for the Neurology, Urology, Lifecycle and HIV business units. Mr. Marshall received his BSBA in Marketing and Economics from Western Carolina University and MBA from Houston Baptist University.

John T. Maxwell has served as our Chief Financial Officer since January 2017. Prior to joining our team, Mr. Maxwell held senior financial roles at WIL Research, InfoNXX, PanAmSat, ADP and General Signal, including as Chief Financial Officer of WIL Research from September 2008 to April 2016. Mr. Maxwell started his career at Ernst & Young, serving in the Dallas, New York and Stamford offices. Mr. Maxwell helped lead the successful strategic sale transactions by the private equity sponsors of WIL Research in April 2016 to Charles River Labs and of PanAmSat in 2006 to Intelsat. Mr. Maxwell also helped lead the initial public offering of PanAmSat in 2005 and multiple public and private debt transactions for WIL Research, InfoNXX and PanAmSat. Mr. Maxwell is a licensed certified public accountant and holds a BBA in Accounting from Texas Tech University and an MBA in Finance and International Business from New York University Stern School of Business.

A. Mark Schobel joined our team in December 2005 and has served as our Chief Innovation and Technology Officer since November 2015. Mr. Schobel served as our Chief Executive Officer and Co-President through November 2014 and has served as a member of our board of directors since November 2005. From 2001 to 2005, he was the Global Head of New Technology and Product Innovation for the Consumer Health Business Unit at Novartis where he pioneered thin film delivery of systemic drugs. Prior to Novartis, Mr. Schobel held various general management positions with Reed & Carnrick Pharmaceuticals, Warner-Lambert and Pharmaceutical Formulations Inc. Mr. Schobel received his BS in Chemistry from Fairleigh Dickinson University and has been awarded 21 patents along with having multiple patents pending in fields ranging from film drug delivery to nanoparticle delivery systems. Our board of directors believes that Mr. Schobel's extensive knowledge of our company, as well as his experience in the biotechnology industry qualifies him to serve on our board of directors.

Theresa Wood has served as the head of our Human Resources function since September 2006. Prior to joining our team, Ms. Wood was the Director, Human Resources, for the Hewlett Packard Financial Services Americas division from 1999 to 2006. From 1995 to 1998, Ms. Wood provided consulting services to several companies in the Financial Services, Healthcare and Consumer Goods market. Prior to that, Ms. Wood spent seven years with Sea-Land Service Corp. Ms. Wood received her BS in Management Science and Marketing from Kean University.

Non-Employee Directors

Douglas Bratton has served as Chairman of our board of directors since January 2004. Mr. Bratton is the Founder, President and Chief Investment Officer of Crestline Investors, an institutional alternative investment management firm. Mr. Bratton has been an investment professional specializing in alternative asset strategies since 1983 and has managed assets on behalf of the Bass family of Fort Worth, Texas, since 1988. Mr. Bratton received a BS from North Carolina State University in 1981 and an MBA with Honors from Duke University in 1984. Mr. Bratton serves on the board of directors of Bounty Minerals Corporation, a private company, and the Board of Visitors of Duke University's Fuqua School of Business. Our board of directors believes that Mr. Bratton's business experience, as well as his strong finance and management background, qualifies him to serve on our board of directors.

Gregory Brown, M.D. has served as a member of our board of directors since March 2007. Dr. Brown is a co-founder and Vice Chairman at HealthCare Royalty Partners, or HCR Partners, and chairs that firm's Senior Advisor Board. Educated as a transplantation immunologist and trained as a thoracic and vascular surgeon, Dr. Brown practiced thoracic and vascular surgery in a community setting where he

also founded and led a health maintenance organization. Before co-founding HCR Partners, Dr. Brown was a partner at Paul Capital Partners, where he co-managed that firm's royalty investments as a member of the royalty management committee. Prior to beginning his principal investment career in 2003, Dr. Brown was co-head of investment banking and head of healthcare at Adams, Harkness & Hill (now Canaccord Genuity) and a ranked biotechnology research analyst at Vector Securities International. Dr. Brown holds a BA from Yale University, an M.D. from SUNY Upstate Medical Center and an MBA from Harvard University. He currently serves on the boards of the following public pharmaceutical companies: Caladrius Biosciences, Inc. (Nasdaq: CLBS) and Cambrex Corporation (NYSE: CBM), and the boards of Faron Pharmaceuticals and Vanderbilt Clinical S.a.r.l. both private companies. Our board of directors believes that Dr. Brown's extensive experience in the pharmaceutical industry and investing in life sciences companies, as well as his medical and scientific background, qualifies him to serve on our board of directors.

John Cochran has served as a member of our board of directors since January 2004. Mr. Cochran has been a partner at Bratton Capital Management L.P. since October 1998, and is responsible for its private equity investments. Mr. Cochran is also a partner and Chief Operating Officer of Crestline Management, a credit-oriented alternative asset management platform. Prior to joining Bratton Capital Management L.P., Mr. Cochran spent 10 years with KPMG focused primarily on audit and merger and acquisition due diligence. Mr. Cochran received his BA in Accounting from Texas Christian University and is also a licensed certified public accountant. Our board of directors believes that Mr. Cochran's private equity investment and company oversight experience along with his strong finance and management background, qualifies him to serve on our board of directors.

Santo Costa has served as a member of our board of directors since December 2015. Since 2007, Mr. Costa has served as Of Counsel to the law firm of Smith, Anderson, Blount, Dorsett, Mitchell and Jernigan, L.L.P. of Raleigh, North Carolina, specializing in corporate law for healthcare companies. Mr. Costa has served on the board of directors of Cytokinetics Inc. (Nasdaq: CYTK) since October 2010, and as the chairman of the board of directors of Metabolon, Inc., a private company, since April 2013. From 1994 to 2001, he held various positions at Quintiles Transnational Corporation, including as Vice Chairman, President and Chief Operating Officer. Prior to joining Quintiles, Mr. Costa spent 23 years in the pharmaceutical industry, most recently as General Counsel and Senior Vice President, Administration with Glaxo Inc. Prior to joining Glaxo, he served as U.S. Area Counsel with Merrell Dow Pharmaceuticals and as Food & Drug Counsel with Norwich Eaton Pharmaceuticals, Inc. Mr. Costa served as Chairman of the board of directors of Alchemia Limited, a private biopharmaceutical company, from March 2014 to June 2015. He also served on the board of directors of Magor Corporation, formerly Biovest Corp. I, from March 2010 until March 2013. He also served as Chairman of the board of directors of LaboPharm, Inc. from March 2006 to November 2011 and a director of OSI Pharmaceuticals from June 2006 to June 2010, as well as serving as a director at other private companies. Mr. Costa earned both a BS in Pharmacy and a JD from St. John's University. Our board of directors believes that Mr. Costa's experience in the biotechnology industry, his broad experience advising financial institutions, global corporations and boards of directors of publicly held companies, and his experience serving as a director of public and private companies, qualifies him to serve on our board of directors.

James S. Scibetta has served as a member of our board of directors since April 2017. Mr. Scibetta has been serving as Chief Executive Officer of Maverick Therapeutics, a development stage immuno-oncology company since July 2017. Prior to Maverick, Mr. Scibetta was appointed President of Pacira Pharmaceuticals, or Pacira (Nasdaq: PCRX), in October 2015, where he oversaw commercial and medical support activities, and directed commercial manufacturing, tech transfer and research and development. Mr. Scibetta served as Pacira's Chief Financial Officer from August 2008 through May 2016 where he led its 2011 initial public offering and subsequent debt and equity financings. Prior to that, Mr. Scibetta served as Chief Financial Officer of Bioenvision Inc., a commercial-stage public oncology company acquired by Genzyme, and Merrimack Pharmaceuticals, an oncology-focused systems biology company. Earlier in his career, Mr. Scibetta spent over a decade in investment banking where he was responsible for sourcing and executing transactions for a broad base of public and private healthcare and life sciences companies. Mr. Scibetta also serves as a director and chairman of the audit committee of Matinas BioPharma Holdings, Inc. (NYSE: MTNB), a biopharmaceutical company. Mr. Scibetta received

his BS in Physics from Wake Forest University and his MBA from the University of Michigan. Our board of directors believes that Mr. Scibetta's extensive senior management experience in the biotechnology industry, as well as his experience on the boards of both public and private companies, qualifies him to serve on our board of directors.

Board Composition

Our business and affairs are organized under the direction of our board of directors, which currently consists of five non-executive members, and two executive members. Our directors may be removed for cause by the affirmative vote of the holders of at least $66^{2/3}$% of our voting stock. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Our board of directors has determined that all of our directors are independent directors, other than Keith J. Kendall and A. Mark Schobel, as defined by Rule 5605(a)(2) of the Nasdaq Listing Rules.

Effective upon the consummation of this offering, we will divide our board of directors into three classes, as follows:

- Class I, which will consist of ;
- Class II, which will consist of ; and
- Class III, which will consist of .

At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized size of our board of directors is currently nine members. The authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in our control or management.

Board Leadership Structure

Our board of directors is currently chaired by Douglas Bratton. As a general policy, our board of directors believes that separation of the positions of Chairman and Chief Executive Officer reinforces the independence of the board of directors from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of the board of directors as a whole. As such, Mr. Kendall serves as our President and Chief Executive Officer, while Douglas Bratton serves as our Chairman of the board of directors, but is not an officer. We expect and intend the positions of Chairman of the board of directors and Chief Executive Officer to continue to be held by two individuals in the future.

Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. The board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and responsibilities described below. From time to time, the board may establish other committees to facilitate the management of our business.

Audit Committee

Our audit committee currently consists of Gregory Brown, M.D., Santo Costa and James S. Scibetta. Immediately following the closing of this offering, our audit committee will consist of , each of whom our board of directors has determined satisfies the Nasdaq Global Market and SEC independence requirements. The chairperson of our audit committee is currently James S. Scibetta, and following the closing of this offering, Mr. Scibetta will continue to serve as the chair of our audit committee. The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent auditors on our engagement team as required by law and considering whether, in order to assure continuing auditor independence, it is appropriate to adopt a policy of rotating the independent auditing firm on a regular basis;
- reviewing relationships that may reasonably be thought to bear on our auditors' independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditors;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," and discussing the statements and reports with our independent auditors and management;
- reviewing with our independent auditors and management significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;
- reviewing with management and our auditors any earnings announcements and other public announcements regarding material developments;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and providing oversight of any related-person transactions and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;
- reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management is implemented; and
- reviewing and evaluating on an annual basis the performance of the audit committee, including compliance of the audit committee with its charter.

Our board of directors has determined that James Scibetta qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the Nasdaq Listing Rules. In making this determination, our board has considered Mr. Scibetta's extensive financial experience and business background. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

Our audit committee will operate under a written charter, to be effective immediately prior to the consummation of this offering, that satisfies the applicable rules of the SEC and the listing standards of the Nasdaq Global Market.

Compensation Committee

Our compensation committee currently consists of John Cochran, Santo Costa and Douglas Bratton, and following the closing of this offering, the committee shall continue to consist of . The chairperson of our compensation committee is currently , and following the closing of this offering, will continue to serve as the chair of our compensation committee. Our board of directors has determined that each of the members of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended, or Exchange Act, is an outside director, as defined pursuant to Section 162(m) of the Code and satisfies the Nasdaq Global Market independence requirements. The functions of this committee includes, among other things:

- reviewing, modifying and approving our overall compensation strategy and policies;
- reviewing and approving the compensation and other terms of employment of our executive officers;
- reviewing and approving performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
- reviewing and approving the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- establishing policies with respect to votes by our stockholders to approve executive compensation as required by Section 14A of the Exchange Act and determining our recommendations regarding the frequency of advisory votes on executive compensation;
- retaining or terminating a compensation consultant or firm to be used to assist the Committee in benchmarking and setting appropriate compensation levels and policies and approving such consultant's or firm's fees and other retention terms;
- approving, modifying and administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements;
- reviewing and approving the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;
- reviewing the adequacy of its charter on a periodic basis;
- preparing the report that the SEC requires in our annual proxy statement; and
- reviewing and assessing on an annual basis the performance of the compensation committee.

Our compensation committee will operate under a written charter, to be effective immediately prior to the consummation of this offering, that satisfies the applicable rules of the SEC and the listing standards of the Nasdaq Global Market.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Douglas Bratton, Gregory Brown and John Cochran, each of whom our board has determined satisfies the Nasdaq Global Market independence requirements. The chairperson of our nominating and corporate governance committee is Douglas Bratton. The functions of this committee includes, among other things:

- identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;
- determining the minimum qualifications for service on our board of directors;
- evaluating, nominating and recommending individuals for membership on our board of directors;

- evaluating nominations by stockholders of candidates for election to our board of directors;
- considering and assessing the independence of members of our board of directors;
- developing a set of corporate governance policies and principles, including a code of business conduct and ethics, periodically reviewing and assessing these policies and principles and their application and recommending to our board of directors any changes to such policies and principles;
- considering questions of possible conflicts of interest of directors as such questions arise;
- reviewing the adequacy of its charter on an annual basis; and
- annually evaluating the performance of the nominating and corporate governance committee.

Our nominating and governance committee will operate under a written charter, to be effective immediately prior to the consummation of this offering that satisfies the applicable rules of the SEC and the listing standards of the Nasdaq Global Market.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has ever been an executive officer or employee of ours. None of our executive officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Code of Business Conduct and Ethics

In connection with this offering, we intend to adopt a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. Following the consummation of this offering, the Code of Conduct will be available on our website at www.aquestive.com. The nominating and corporate governance committee of our board of directors will be responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website.

EXECUTIVE AND DIRECTOR COMPENSATION

Our named executive officers for the fiscal year ended December 31, 2017, which consist of our principal executive officer and the next two most highly compensated executive officers who were serving as executive officers as of December 31, 2017, are:

Keith J. Kendall, our President and Chief Executive Officer;

John T. Maxwell, our Chief Financial Officer; and

A. Mark Schobel, our Chief Innovation and Technology Officer.

Summary Compensation Table

The following table provides information regarding the compensation provided to our named executive officers during the fiscal year ended December 31, 2017:

Name and Principal Position	Year	Salary ($)[1]	Bonus ($)	Stock Awards ($)[2]	Non-Equity Incentive Plan Compensation ($)[3]	All Other Compensation ($)	Total Compensation ($)
Keith J. Kendall *President and Chief Executive Officer*	2017	400,000	—	—	525,000	24,769(4)	949,769
John T. Maxwell[7] *Chief Financial Officer*	2017	350,000	70,000(8)	—	306,250	19,615(5)	745,865
A. Mark Schobel *Chief Innovation & Technology Officer*	2017	350,000	—	—	367,500	21,590(6)	739,090

(1) See “Narrative to the Summary Compensation Table” below.

(2) This column reflects the aggregate grant date fair value of the awards granted under the PUP Plans during 2017, calculated in accordance with FASB Accounting Standards Codification Topic 718 Compensation — Stock Compensation (“ASC Topic 718”), and assumes no forfeiture rate derived in the calculation of the grant date fair value of these awards. The assumptions used in calculating the grant date fair value of these awards are set forth in Note 17 to our audited consolidated financial statements included in this prospectus. Because of the contingency of the events that must occur in order for PUP Plan awards to be settled, no compensation expense was recorded because it was not probable at the time of grant that the performance requirements would be met. If, at the time of grant, such performance was probable, the grant date value of the PUP Plan awards granted in 2017 would have been $1,178,666 for Mr. Kendall, $874,335 for Mr. Maxwell and $56,115 for Mr. Schobel.

(3) The amounts in this column represent performance bonuses earned by the named executive officers in the calendar year 2016 based upon the achievement of pre-established performance objectives. See “— Annual Bonus Compensation” below.

(4) Includes Company contributions to the named executive officer’s 401(k) plan account ($16,200) and disability insurance benefits ($8,569).

(5) Includes Company contributions to the named executive officer’s 401(k) plan account ($16,200) and disability insurance benefits ($3,415).

(6) Includes Company contributions to the named executive officer’s 401(k) plan account ($16,200) and disability insurance benefits ($5,390).

(7) Mr. Maxwell commenced his employment on January 9, 2017.

(8) Includes a sign-on bonus of $70,000 paid to Mr. Maxwell upon commencement of his employment on January 9, 2017 pursuant to his employment agreement.

Narrative to the Summary Compensation Table

Our Compensation Committee reviews compensation annually for our named executive officers and uses base salaries to recognize the experience, skills, knowledge and responsibilities required of our named executive officers. In setting executive base salaries and bonuses, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our executives to achieve short-and long-term results that are in the best interests of our stockholders, and a long-term commitment to our company. None of our named executive officers currently has an employment agreement or other agreement or arrangement that specifically provides for automatic or scheduled increases in base salary.

The Compensation Committee has historically determined our named executive officers' compensation and has typically reviewed and discussed, on an annual basis, management's proposed compensation with our president and chief executive officer for all our named executive officers (other than for our president and chief executive officer). Based on those discussions and its discretion, the Compensation Committee and our full board of directors then approved the compensation of each named executive officer. Upon the completion of this offering, the Compensation Committee will continue to determine our named executive officers' compensation following this process and will approve the compensation of each of our named executive officers.

Annual Base Salary

Base salaries for our named executive officers are initially established through arm's-length negotiations at the time of the named executive officer's hiring, taking into account such named executive officer's qualifications, experience, prior salary, the scope of the named executive officer's responsibilities and competitive market compensation paid by other companies for similar positions within the industry. The chart below reflects the base salaries approved by our board of directors and Compensation Committee for our named executive officers during fiscal year ended December 31, 2017.

Name	2017 Base Salary ($)
Keith J. Kendall	400,000
John T. Maxwell	350,000
A. Mark Schobel	350,000

Annual Bonus Compensation

We have an annual objective-setting and review process for our named executive officers that is the basis for the determination of potential annual bonuses for our named executive officers. Our employment agreements with our named executive officers provide that they will be eligible for annual performance-based bonuses up to a specific target percentage of their salary based on the Compensation Committee's assessment of their and the Company's performance against goals established by the Compensation Committee. Our Compensation Committee sets our annual objectives which are based in part on our revenue and EBITDA for the year as well as the individual objectives of each employee which are focused on each employee's specific performance relative to the Company's achievements as a whole.

The target bonus opportunities for our named executive officers for fiscal year 2017, expressed as a percentage of their annual base salary, were 75% for Mr. Kendall, 50% for Mr. Maxwell and 75% for Mr. Schobel.

As previously discussed, our Compensation Committee sets our annual objectives which are based in part on our revenue and EBITDA for the year as well as the individual objectives of each employee which are focused on each employee's specific performance relative to the Company's achievements as a whole. The Compensation Committee determined that the Company achieved the annual objectives for the fiscal year 2017.

Employment Agreements with Our Named Executive Officers

We entered into an employment agreement with each of Keith J. Kendall, our President and Chief Executive Officer, and A. Mark Schobel, our Chief Innovation and Technology Officer, on November 17, 2008. We entered into an employment agreement with John T. Maxwell, our Chief Financial Officer, on January 9, 2017. These agreements set forth the initial terms and conditions of each executive's employment with us, including base salary, target annual bonus opportunity and standard employee benefit plan participation. These employment agreements provide for "at will" employment. The material terms of these employment agreements with our named executive officers are described below. The terms "cause," "good reason" and "change in control" referred to below are defined in each named executive officer's employment agreement.

Keith J. Kendall

The term of employment for Mr. Kendall under his employment agreement renews annually, unless we give him prior written notice of non-renewal or until his employment with us terminates for any reason.

Mr. Kendall's base salary for 2017 was equal to $400,000, his annual target incentive compensation is equal to 75% of his base salary, and he is eligible to participate in our benefit plans as in effect from time to time. His base salary and target bonus opportunity is subject to annual review and adjustment. His bonus award will be made at the discretion of the Compensation Committee. His employment agreement provides that he agrees to grant us certain intellectual property rights. His employment agreement includes additional provisions that require him to refrain from competing with our business, soliciting or interfering with our suppliers, customers, prospective customers and other business relationships, and from soliciting, hiring or otherwise interfering with our relationship with any person employed or previously employed by us, with the duration of such restrictions to last during his employment and for 18 months thereafter. Pursuant to his employment agreement, upon the effectiveness of this offering, Mr. Kendall is entitled to receive stock appreciation rights equal to (i) 5% of our common stock outstanding following the consummation of this offering on a fully diluted basis, minus any shares of common stock he receives upon the expected termination of our PUP Plans in April 2018 and (ii) restricted stock equal to 0.24% of our common stock outstanding following the consummation of this offering on a fully diluted basis, each of which will be granted under the 2018 Plan. The stock appreciation rights will vest in 36 equal monthly installments beginning on the last day of the month next following the month in which this offering is completed and the restricted stock will vest in eight equal quarterly installments beginning on the last day of the month next following the month in which this offering is completed.

In the event Mr. Kendall's employment is terminated by the Company for "cause", he will be entitled to receive his salary and benefits that had accrued but had remained unpaid through the date of termination, or the Accrued Payments.

In the event that Mr. Kendall's employment is terminated by reason of death or disability, in addition to the Accrued Payments, he will be entitled to a cash payment consisting of an amount equal to (i) his unpaid annual bonus earned for the year preceding the year in which his employment terminated, (ii) any accrued and unused vacation pay for the year in which his employment terminated, (iii) a portion of his target annual bonus for the year in which his employment terminated, pro-rated for the number of days he was employed during the year in which his employment terminated, and (iv) accelerated vesting of his outstanding unvested equity-based compensation awards as if he had continued being employed through the end of the year in which his employment terminated, or, in the case of awards subject to "cliff vesting," pro-rata accelerated vesting based on the percentage of the vesting period that had elapsed as of the date of his termination. Additionally, Mr. Kendall will be able to exercise any equity awards that vest upon the termination of his employment for one year following such termination.

In the event that Mr. Kendall's employment is terminated by us without "cause" or he terminates his employment for "good reason", and subject to the delivery of a fully effective release of claims and continued compliance with his restrictive covenant obligations, in addition to the Accrued Payments, he will be entitled to receive (i) a cash payment of an amount equal to his unpaid annual bonus earned for the year preceding the year in which his employment terminated, (ii) a cash payment of an amount equal to any accrued and unused vacation pay for the year in which his employment terminated, (iii) a cash payment consisting of an amount equal to a portion of his target annual bonus for the year in which his employment terminated, pro-rated for the number of days he was employed during the year in which his employment terminated, (iv) monthly payments for a period of 18 months following the termination of his employment, with each monthly payment equal to 1/12 of the sum of his base salary and target annual bonus, (v) for 18 months following the termination of his employment, continuing coverage under our group health and life insurance plans in which he was a participant immediately prior to the termination of his employment, at the same levels and on the same terms and conditions as are provided to similarly situated executives, and (vi) full and immediate vesting of all outstanding unvested equity-based compensation awards, and any equity compensation awards that are or become vested upon termination of his employment remain exercisable for at least one year after the date of termination or, if earlier, until the expiration of the stated term of the award.

If Mr. Kendall's employment is terminated by us without "cause" or he terminates his employment for good reason, in each case during the period beginning 180 days before and ending 24 months following the effective date of a change in control, then subject to the delivery of a fully effective release of claims and continued compliance with his respective restrictive covenant obligations, he will be entitled to all the

severance that he would have received had his employment been terminated by the Company not for cause or by him for good reason, provided that, in lieu of the payments described in section (iv) of the paragraph immediately above, Mr. Kendall will be entitled to receive an immediate lump sum cash payment of an amount equal to 2.75 times the sum of his base salary and target annual bonus, and, with respect to the benefit continuation described in section (v) of the paragraph immediately above, such benefits shall continue for a period of 33 months following termination.

Additionally, pursuant to his employment agreement, in the event that payments to or for the benefit of Mr. Kendall relating to a change in control would be subject to an excise tax imposed by Section 4999 of the Internal Revenue Code, the aggregate amount of such payments will be increased so that, after the payment of taxes, he will be in the same position as he would have been had he not been required to pay such excise taxes. Additionally, in the event that the continuation of coverage under our group health plan triggers taxable income to Mr. Kendall, the Company will pay him additional cash payments as are necessary for him to receive the same net after-tax benefits that he would have received under such plans if he had continued to receive such plan benefits while employed with the Company.

Under the terms of the PUP Plans prior to its termination, all awards granted thereunder become fully vested and payable upon a change in control.

John T. Maxwell

The term of employment for Mr. Maxwell under his employment agreement ends on January 9, 2019, and will thereafter renew annually unless we give prior written notice of non-renewal or until Mr. Maxwell's employment with us terminates for any reason. Mr. Maxwell's base salary for 2017 was $350,000, his annual target incentive compensation is equal to 50% of his base salary, and he is eligible to participate in our benefit plans as in effect from time to time. His base salary and target bonus opportunity is subject to annual review and adjustment. His bonus award will be made at the discretion of the Compensation Committee. Mr. Maxwell was entitled to a one-time lump sum signing bonus of $70,000, which was paid with the first regular payroll following the effective date of his employment agreement. His employment agreement provides that he agrees to grant us certain intellectual property rights. His employment agreement includes additional provisions that require him to refrain from competing with our business, soliciting or interfering with our suppliers, customers, prospective customers and other business relationships, and from soliciting, hiring or otherwise interfering with our relationship with any person employed or previously employed by us, with the duration of such restrictions to last during his employment and for 12 months thereafter.

In the event Mr. Maxwell's employment is terminated by the Company for "cause, he will be entitled to receive Accrued Payments through the date of termination.

In the event that Mr. Maxwell's employment is terminated by reason of death or disability, in addition to the Accrued Payments, he will be entitled to a cash payment consisting of an amount equal to a portion of the bonus he received for the year prior to the year of his termination, pro-rated for the number of days he was actively working during the year of termination through the effective date of termination.

In the event that Mr. Maxwell's employment is terminated by us without "causeor he terminates his employment for "good reason, and subject to the delivery of a fully effective release of claims and continued compliance with his restrictive covenant obligations, in addition to the Accrued Payments, he will be entitled to (i) continued base salary for a period of 12 months, in equal installments in accordance with our normal payroll practices and (ii) for a period of 12 months following the termination of his employment continuing coverage under our group health and life insurance plans in which he was a participant immediately prior to the termination of his employment.

Under the terms of our Performance Unit Plans, or PUP Plans, prior to its termination, all awards granted thereunder become fully vested and payable upon a change in control.

A. Mark Schobel

The term of employment for Mr. Schobel under his employment agreement renews annually, unless we give him prior written notice of non-renewal or until his employment with us terminates for any reason. Mr. Schobel's base salary for 2017 was equal to $350,000, his annual target incentive compensation is

equal to 75% of his base salary, and he is be eligible to participate in our benefit plans as in effect from time to time. His base salary and target bonus opportunity is subject to annual review and adjustment. His bonus award will be made at the discretion of the Compensation Committee. His employment agreement provides that he agrees to grant us certain intellectual property rights. His employment agreement includes additional provisions that require him to refrain from competing with our business, soliciting or interfering with our suppliers, customers, prospective customers and other business relationships, and from soliciting, hiring or otherwise interfering with our relationship with any person employed or previously employed by us, with the duration of such restrictions to last during his employment and for 18 months thereafter. Pursuant to his employment agreement, upon the effectiveness of this offering, Mr. Schobel is entitled to receive stock appreciation rights equal to (i) 5% of our common stock outstanding following the consummation of this offering on a fully diluted basis, minus any shares of common stock he receives upon the expected termination of our PUP Plans in April 2018 and (ii) restricted stock equal to 0.47% of our common stock outstanding following the consummation of this offering on a fully diluted basis, each of which will be granted under the 2018 Plan. The stock appreciation rights will vest in 36 equal monthly installments beginning on the last day of the month next following the month in which this offering is completed and the restricted stock will vest in eight equal quarterly installments beginning on the last day of the month next following the month in which this offering is completed.

In the event Mr. Schobel's employment is terminated by the Company for "cause," he will be entitled to receive Accrued Payments through the date of termination.

In the event that Mr. Schobel's employment is terminated by reason of death or disability, in addition to the Accrued Payments, he will be entitled to a cash payment consisting of an amount equal to (i) his unpaid annual bonus earned for the year preceding the year in which his employment terminated, (ii) any accrued and unused vacation pay for the year in which his employment terminated, (iii) a portion of his target annual bonus for the year in which his employment terminated, pro-rated for the number of days he was employed during the year in which his employment terminated, and (iv) accelerated vesting of his outstanding unvested equity-based compensation awards as if he had continued being employed through the end of the year in which his employment terminated, or, in the case of awards subject to "cliff vesting," pro-rata accelerated vesting based on the percentage of the vesting period that had elapsed as of the date of his termination. Additionally, Mr. Schobel will be able to exercise any equity awards that vest upon the termination of his employment for one year following such termination.

In the event that Mr. Schobel's employment is terminated by us without "cause" or he terminates his employment for "good reason," and subject to the delivery of a fully effective release of claims and continued compliance with his restrictive covenant obligations, he will be entitled to receive (i) a cash payment of an amount equal to his unpaid annual bonus earned for the year preceding the year in which his employment terminated, (ii) a cash payment of an amount equal to any accrued and unused vacation pay for the year in which his employment terminated, (iii) a cash payment consisting of an amount equal to a portion of his target annual bonus for the year in which his employment was terminated, pro-rated for the number of days he was employed during the year in which his employment terminated, (iv) monthly payments for a period of 18 months following the termination of his employment, with each monthly payment equal to 1/12 of the sum of his base salary and target annual bonus, (v) for 18 months following the termination of his employment, continuing coverage under our group health and life insurance plans in which he was a participant immediately prior to the termination of his employment, at the same levels and on the same terms and conditions as are provided to similarly situated executives, and (vi) full and immediate vesting of all outstanding unvested equity-based compensation awards, and any equity compensation awards that are or become vested upon termination of his employment remain exercisable for at least one year after the date of termination or, if earlier, until the expiration of the stated term of the award.

If Mr. Schobel's employment is terminated by us without cause or he terminates his employment for good reason, in each case during the period beginning 180 days before and 24 months following the effective date of a change in control, then subject to the delivery of a fully effective release of claims and continued compliance with his respective restrictive covenant obligations, in addition to the Accrued Payments he will be entitled to all the severance that he would have received had his employment been terminated by the Company not for cause or by him for good reason, provided that, in lieu of the

payments described in section (iv) of the paragraph immediately above, Mr. Schobel will be entitled to receive an immediate cash payment of an amount consisting of three times the sum of his base salary and target annual bonus, and, with respect to the benefit continuation described in section (v) of the paragraph immediately above, such benefits shall continue until the third anniversary of such date of termination.

Additionally, pursuant to his employment agreement, in the event that payments to or for the benefit of Mr. Schobel relating to a change in control would be subject to an excise tax imposed by Section 4999 of the Internal Revenue Code, the aggregate amount of such payments will be increased so that, after the payment of taxes, he will be in the same position as he would have been had he not been required to pay such excise taxes. Additionally, in the event that the continuation of coverage under our group health plan triggers taxable income to Mr. Schobel, the Company will pay him additional cash payments as are necessary for him to receive the same net after-tax benefits that he would have received under such plans if he had continued to receive such plan benefits while employed with the Company.

Under the terms of the PUP Plan prior to its termination, all awards granted thereunder become fully vested and payable upon a change in control.

Outstanding Equity Awards at December 31, 2017

The following table provides information about the number of outstanding equity awards held by our named executive officers at December 31, 2017.

		Stock Awards	
Name	Grant Date	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)[1]	Equity Incentive Plan Awards: Market Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)[2]
Keith J. Kendall	January 13, 2017	122,162	35,857
	January 1, 2017	2,443,249	717,377
	December 18, 2015	202,201	66,453
	August 1, 2010	2,392,698	1,000,217
	October 21, 2008	2,462,136	1,275,257
	June 16, 2006	4,715,961	1,934,023
John T. Maxwell	January 9, 2017	1,710,274	589,837
A. Mark Schobel	January 13, 2017	122,162	35,857
	December 18, 2015	252,750	83,066
	August 1, 2010	2,392,698	1,000,217
	October 21, 2008	3,282,848	1,700,342
	September 21, 2006	2,453,872	882,036
	June 16, 2006	114,755	47,061
	March 22, 2006	91,175	55,135
	February 13, 2006	1,468,235	887,877
	November 17, 2005	2,159,910	1,476,596

(1) PUP awards vest at varying rates from immediate to time-based over three years, depending on the specific grant and the agreement with the employee. Upon termination of the PUP Plans, vesting of all outstanding awards will be accelerated. None of these grants are payable until certain performance conditions have been met, and none of these conditions were met as of this date.

(2) Market value is based on a third party valuation of the Company as of December 31, 2017 and is net of the base value of each grant.

Equity-Based Incentive Awards

Historically, the equity-based awards we granted to our named executive officers were units in our PUP Plans. The purpose of the PUP Plans, which was originally instituted by us in 2004 when we were organized as a limited liability company, was to reward executives and employees for appreciation in the enterprise value of Aquestive.

Under the PUP Plans, a grantee would receive a grant of units that would entitle him or her to a percentage of the appreciation in value of the Company above a base value. Units granted under the PUP Plans are not actual equity securities in the Company and did not convey any ownership interest on the grantee unless and until they were settled in securities. These grants would vest over time and on a distribution event (*e.g.* change of control, initial public offering or dissolution or liquidation of the Company), could be settled in cash or equity securities.

With respect to the 2017 fiscal year, the Company granted the number of units under the PUP Plans to the named executive officers as set forth in the table below. These units vest over three years, generally subject to the named executive officer's continued employment with us on the applicable vesting date (except as provided above in the section titled "Employment Agreements with Our Named Executive Officers").

Named Executive Officer	Number of Units Granted	Base Value ($)
Mr. Kendall	2,565,412	116,261,261
Mr. Maxwell	1,710,274	103,594,973
Mr. Schobel	122,162	116,269,405

Our board of directors is expected to terminate the PUP Plans. In termination thereof, each award granted under the PUP Plans will become fully vested and each award holder will receive a number of shares of our non-voting common stock equal to the number of units held without regard to the base value, plus an additional payment designed to compensate the grantee for any taxes owed with respect to the shares of non-voting common stock received upon such termination. These non-voting shares will become regular voting common stock at the time of the initial public offering. For our named executive officers, this is expected to result in the following distributions:

Named Executive Officer	Number of Shares of Non-Voting Common Stock Granted (#)	Other Payment Amounts ($)
Mr. Kendall	12,338,408	1,397,030
Mr. Maxwell	1,710,274	127,406
Mr. Schobel	12,338,408	1,397,030

Following this offering, we expect to grant equity incentive compensation to our employees, including the named executive officers, pursuant to the 2018 Plan, which is described in detail below in the section titled "2018 Plan." Although we do not have a formal policy with respect to the grant of equity incentive awards to our named executive officers, or any formal equity ownership guidelines applicable to them, we believe that equity grants will provide our named executive officers with a strong link to our long-term performance, create an ownership culture and help to align the interests of our named executive officers and our stockholders. In addition, we believe that equity grants with a time-based vesting feature will promote executive retention because this feature incentivizes our named executive officers to remain in our employment during the vesting period. Accordingly, our Compensation Committee plans to periodically review the equity incentive compensation of our named executive officers and from time to time expects to grant equity incentive awards.

2018 Equity Incentive Plan

Prior to the consummation of this offering, we intend to adopt the 2018 Plan. The purpose of the 2018 Plan is to assist the Company and its subsidiaries in attracting and retaining valued employees, consultants and non-employee directors by offering them a greater stake in our success and a closer identity with us, and to encourage ownership of the Company's common stock by such employees, consultants and non-employee directors. Under the 2018 Plan, we may grant awards in respect of shares of common stock, or Awards, to employees, directors and consultants of the Company and its subsidiaries. Awards may consist of options, stock appreciation rights, or SARs, restricted stock, restricted stock units, or RSUs, performance stock, performance stock units, or PSUs, and other stock-based awards. Each Award will be governed by the provisions of the 2018 Plan and the applicable award agreement.

Eligibility

Any employee, director or consultant of the Company or any of its subsidiaries is eligible to receive Awards under the 2018 Plan.

Administration

The 2018 Plan will be administered by the Compensation Committee. Awards granted to non-employee members of the board of directors shall be administered by the board of directors. The Compensation Committee will have full and final authority in its discretion to: (i) select the employees, non-employee directors and consultants who will receive Awards, provided that Awards to non-employee directors will be subject to ratification by the board of directors; (ii) determine the type or types of Awards to be granted to each participant; (iii) determine the number of shares to which an Award will relate, the terms and conditions of any Award (including, but not limited to, restrictions as to vesting, performance goals relating to an Award, transferability or forfeiture, exercisability or settlement of an Award, waivers or accelerations thereof and waivers of or modifications to performance goals relating to an Award) and all other matters to be determined in connection with an Award; (iv) determine the strike price, grant price or purchase price (if any) of an Award; (v) determine whether, to what extent, and under what circumstances an Award may be cancelled, forfeited, or surrendered; (vi) determine whether, and to certify that, performance goals to which an Award is subject are satisfied; (vii) determine whether participants will be permitted to defer the settlement of certain Awards; (viii) correct any defect or supply any omission or reconcile any inconsistency in the 2018 Plan and Award agreements thereunder, and to adopt, amend and rescind such rules, regulations, guidelines, forms of agreements and instruments as, in its opinion, may be advisable; (ix) construe and interpret the 2018 Plan and Award agreements thereunder, and (x) make all other determinations as it may deem necessary or advisable for the administration of the 2018 Plan and Award agreements. The Compensation Committee may delegate some or all of its powers to any of our executive officers or any other person, other than its authority to grant awards to certain individuals (such as board members and executive officers).

Shares Available Under the 2018 Plan

Subject to adjustment as provided in the 2018 Plan, the total number of shares available for Awards under the 2018 Plan as of the effective date of the 2018 Plan shall be , or the Plan Limit; provided, however, that on January 1, 2019 and each January 1st thereafter prior to the termination of the 2018 Plan, the Plan Limit shall be increased by the lesser of (x) % of the number of shares of common stock outstanding as of the immediately preceding December 31st and (y) such lesser number as the board of directors may determine in its discretion. Up to shares available for Awards under the 2018 Plan may be issued pursuant to incentive stock options, or the ISO Limit, provided that on January 1, 2019 and each January 1st thereafter prior to the termination of the 2018 Plan, the ISO Limit shall be increased by the lesser of (x) % of the number of shares of common stock outstanding as of the immediately preceding December 31st, (y) shares and (z) such lesser number as the board of directors may determine in its discretion. The maximum number of shares underlying Awards that any non-employee director on the board of directors may be granted during any calendar year is , except that Awards covering up to additional shares may be granted to any such non-employee director in connection with his or her appointment. For purposes of determining the number of shares available for Awards under the 2018 Plan, each stock-settled SAR shall count against the Plan Limit based on the number of shares underlying the exercised portion of such SAR rather than the number of shares issued in settlement of such SAR. Any shares tendered, with the Committee's approval, by a participant in payment of an exercise price for an Award or the tax liability with respect to an Award, including shares withheld from any such Award, shall be available for future Awards hereunder. Shares awarded under the Plan may be reserved or made available from the Company's authorized and unissued common stock or from common stock reacquired and held in the Company's treasury. Any shares issued by the Company through the assumption or substitution of outstanding grants from an acquired company shall not reduce the shares available for Awards under the 2018 Plan. If any shares subject to an Award under the 2018 Plan are forfeited or such Award otherwise terminates for any reason whatsoever without an actual distribution of shares to the participant, any shares counted against the number of shares available for issuance pursuant to the 2018 Plan with respect to such Award shall, to the extent of any such forfeiture or

termination, be added back to the Plan Limit and shall again be available for Awards under the 2018 Plan; provided, however, that the Committee may adopt procedures for the counting of shares relating to any Award to ensure appropriate counting, avoid double counting, provide for adjustments in any case in which the number of shares actually distributed differs from the number of shares previously counted in connection with such Award, and if necessary, to comply with applicable law or regulations.

Awards

Awards that can be granted under the 2018 Plan include restricted stock, RSUs, stock options, SARs, and other stock-based awards.

Performance Goals

In the discretion of the Compensation Committee, the vesting, earning or settlement of any Award may be conditioned upon the achievement of specified performance goals that are substantially uncertain to be met during the applicable performance period at the time such goals are established.

Types of Awards

Options. Options give a participant the right to purchase a specified number of shares from the Company for a specified time period at a fixed price. Options may be either ISOs or non-qualified options, however, ISOs may only be granted to employees of the Company and its subsidiaries. The price at which shares may be purchased upon exercise may not be less than the fair market value of one share on the grant date, or, in the case of an ISO granted to a more than ten percent stockholder, less than 110% of the fair market value of a share on the grant date. The Compensation Committee may grant options that have a term of up to ten years, or, in the case of an ISO granted to a more than ten percent stockholder, five years. The Award agreement will specify the exercise price, term, vesting requirements, including any performance goals, and any other terms and conditions applicable to the option.

Stock Appreciation Rights. A grant of a SAR entitles a participant to receive, upon exercise of the SAR, the excess of (i) the fair market value of one share on the date of exercise, over (ii) the grant price of the SAR as determined by the Compensation Committee. No payment from the participant is required upon the exercise of a SAR. The Compensation Committee will determine and specify in each Award agreement the number of SARs granted, the grant price of the SAR (which may not be less than 100% of the fair market value of a share on the grant date), the time or times at which a SAR may be exercised in whole or in part, the method by which shares will be delivered or deemed to be delivered to a participant, the term of the SAR (which may not be greater than 10 years) and any other terms and conditions of the SAR.

Restricted Stock. An Award of restricted stock is a grant of a specified number of shares, which shares are subject to forfeiture upon the occurrence of certain events during a specified restriction period. Each Award of restricted stock will specify the duration of the restriction period, the conditions under which the shares may be forfeited, and the amount, if any, the participant must pay to receive the shares. Generally, during the restriction period, the participant will have all of the rights of a stockholder with respect to the restricted stock, including the right to vote the shares of restricted stock and to receive dividends. However, dividends may, at the discretion of the Compensation Committee, be paid currently or subject to the same restrictions as the underlying stock (and the Compensation Committee may withhold cash dividends paid on restricted stock until the applicable restrictions have lapsed), provided that, dividends paid on unvested restricted stock that is subject to performance goals will not be paid or released until the applicable performance goals have been achieved.

Restricted Stock Units. An Award of RSUs is a grant of the right to receive a payment in shares or cash, or a combination thereof, equal to the fair market value of a share on the applicable settlement date. RSUs are solely a device for determining amounts to be paid to a participant, do not constitute shares, and will not be treated as a trust fund of any kind. Prior to the settlement of an award and the receipt of shares, the participant will have no rights as a stockholder with respect to any such shares. Notwithstanding the previous sentence, the Compensation Committee may provide in an Award agreement that amounts equal to dividends declared during the restriction period on the shares covered by the Award will be credited to the participant’s account and settled in shares at the same time as the

RSUs to which such dividend equivalents relate. Awards of RSUs will be settled in shares, unless otherwise provided in an Award agreement. Unless otherwise provided in an Award Agreement, subject to the Participant's continued employment or other service with us from the grant date through the expiration of the restriction period, the vested portion of an Award of RSUs will be settled within 60 days after the expiration of the restriction period.

Performance Stock. An Award of performance stock generally is the same as an Award of restricted stock, as described above, but vesting is conditional on the achievement of one or more performance goals during a performance period.

Performance Stock Units. An Award of performance stock units generally is the same as an Award of restricted stock units, as described above, but vesting and settlement are conditional on the achievement of one or more performance goals during a performance period.

Other Stock-Based Awards. The Compensation Committee may grant, subject to applicable law, any other type of Award under the 2018 Plan that is payable in, or valued in whole or in part by reference to, shares, and that is deemed by the Compensation Committee to be consistent with the purposes of the 2018 Plan, including, without limitation, fully vested shares and dividend equivalents.

Termination of Employment of Service

Unless otherwise provided in an Award agreement or an effective employment, consulting, severance or similar agreement with the Company or a subsidiary, or as otherwise provided below in the section titled "Change in Control and Other Corporate Transactions," upon a participant's termination of employment or service, the unvested portion of such participant's Awards will cease to vest and will be forfeited (with no compensation due to the participant) and the vested portion of such participant's options and SARs will remain exercisable for a period of (i) 90 days in the event of a termination without cause, (ii) one year in the event of a termination due to death or disability and (iii) 90 days in the event of a participant's resignation; provided, however, no option or SAR will be exercisable after its stated term has expired. All of a participant's options and SARs, whether or not vested, will be forfeited immediately upon a termination for cause, with no compensation due to the participant.

Change in Control and Other Corporate Transactions

Unless otherwise provided in an Award agreement or an effective employment, consulting, severance or other similar agreement with the Company or one of its subsidiaries, a change in control will not, in and of itself, accelerate the vesting, settlement, or exercisability of outstanding Awards. Notwithstanding the foregoing and unless otherwise provided in an Award agreement or an effective employment, consulting, severance or similar agreement with the Company or a subsidiary, if (i) the successor corporation (or its direct or indirect parent) does not agree to assume an outstanding Award or does not agree to substitute or replace such Award, in either case, with an award involving the registered and publicly traded ordinary equity securities of such successor corporation (or its direct or indirect parent) on terms and conditions necessary to preserve the rights of the applicable participant with respect to such Award or (ii) the change in control is not approved by a majority of the board of directors immediately prior to such change in control, then the Compensation Committee, in its sole discretion, may take one or more of the following actions with respect to all, some or any such Awards: (a) accelerate the vesting and, if applicable, exercisability of such Awards such that the Awards are fully vested and, if applicable, exercisable (effective immediately prior to such change in control); (b) with respect to any Awards that do not constitute "non-qualified deferred compensation" within the meaning of Section 409A of the Code, accelerate the settlement of such Awards upon such change in control; (c) with respect to Awards that constitute "non-qualified deferred compensation" within the meaning of Section 409A of the Code, terminate all such Awards and settle all such Awards for a cash payment equal to the fair market value of the shares underlying such Awards less the amount the participant is required to pay for such shares, if any, provided that (I) such change in control satisfies the requirements of Treasury Regulation Section 1.409A-3(i)(5)(v), (vi) or (vii) and (II) all other arrangements that would be aggregated with such Awards under Section 409A of the Code are terminated and liquidated within 30 days before or 12 months after such change in control; (d) cancel outstanding options or SARs in exchange for a cash payment in an amount equal to the excess, if any, of the fair market value of the shares underlying the

unexercised portion of the option or SAR as of the date of the change in control over the exercise price or grant price, as the case may be, of such portion, provided that any option or SAR with a per share exercise price or grant price, as the case may be, that equals or exceeds the fair market value of one share on the date of the change in control will be cancelled with no payment due the participant; and (e) take such other actions as the Compensation Committee deems appropriate. If any action is taken with respect to any Award under items (a) through (e) and such Award is subject to performance goals, such performance goals shall be deemed satisfied based on the actual level of achievement of the applicable performance goals through the date of the change in control or, if determined by the Compensation Committee in its sole discretion prior to such change in control, using the applicable target level of achievement rather than such actual level of achievement.

Unless provided otherwise in an Award agreement, or an effective employment, consulting, severance or other similar agreement, or as otherwise may be determined by the Compensation Committee prior to a change in control, in the event that Awards are assumed in connection with a change in control or substituted with new awards, and a participant's employment or other service with the Company and its subsidiaries is terminated by the Company without cause or due to disability, as the result of the participant's death or by the participant for good reason, in any case, within 24 months following a change in control, then generally (i) the unvested portion of such participant's Awards will vest in full (with any applicable performance goals being deemed to have been achieved at target or, if greater, actual levels of performance), (ii) Awards of options and SARs will remain exercisable by the participant or the participant's beneficiary or legal representative, as the case may be, for a period of one-year (but not beyond the stated term of the option or SAR), (iii) all RSUs and PSUs will be settled within 30 days after such termination and (iv) all other stock-based awards will be settled within 30 days after such termination.

In the event of a share dividend, recapitalization, forward share split, reverse share split, reorganization, spin-off, extraordinary or unusual cash distribution, or other similar non-reciprocal corporate transaction or event between the Company and its shareholders, the Compensation Committee will make equitable adjustments in (i) the number and kind of shares which may thereafter be issued in connection with Awards, (ii) the number and kind of shares issuable in respect of outstanding Awards, (iii) the aggregate number and kind of shares available under the 2018 Plan, and (iv) the exercise or grant price relating to any Award, or if deemed appropriate, the Compensation Committee may also make provision for a cash payment with respect to any outstanding Award.

Clawback and Recoupment

Any Award granted under the 2018 Plan (and all shares acquired thereunder) will be subject to mandatory repayment and clawback pursuant to the terms of the Company's clawback policy, if any, and as may otherwise be required by any federal or state laws or the rules of any applicable securities exchange. Additional recoupment and clawback policies may be provided in the participant's Award agreement.

Restrictions on Transfer

The 2018 Plan prohibits participants from pledging, encumbering, assigning or transferring any Award, right or interest under the 2018 Plan, except for assignments or transfers that occur by way of the laws of descent and distribution. Awards and rights under the 2018 Plan will be exercisable during the life of a participant only by the participant or his legal guardian. However, the Compensation Committee, may in its discretion, permit transfers of options, SARs, performance stock and/or restricted stock to certain immediate family members of the participant, to trusts for the benefits of such family members and to partnerships in which such family members are the only partners.

Non-U.S. Participants

Without amending the 2018 Plan, Awards may be granted to participants who are foreign nationals or are employed or providing services outside the United States or both, on such terms and conditions different from those specified in the 2018 Plan as may, in the judgment of the Compensation Committee, be necessary or desirable to further the purpose of the 2018 Plan. Moreover, the Compensation

Committee may approve such supplements to, or amendments, restatements or alternative versions of, the 2018 Plan as it may consider necessary or appropriate for such purposes without thereby affecting the terms of the 2018 Plan as in effect for any other purpose.

Amendment and Termination

The board of directors may amend, alter, suspend, discontinue or terminate the 2018 Plan without the consent of our stockholders, except that the board of directors must obtain stockholder approval for actions that would: (i) increase the number of shares subject to the 2018 Plan; (ii) decrease the price at which Awards may be granted; or (iii) require stockholder approval under any applicable federal, state or foreign law or regulation or the rules of any stock exchange or automated quotation system on which shares are then listed or quoted. However, without prior written consent of an affected participant, no amendment, alteration, suspension, discontinuation or termination of the 2018 Plan may materially and adversely affect the rights of a participant under any outstanding Award unless such action is required by law or regulation, or the rules of any applicable securities exchange or automated quotation system. No underwater Option or underwater SAR may be repriced, replaced or regranted through cancellation or purchased for cash without the approval of our stockholders.

Unless earlier terminated, the 2018 Plan will terminate with respect to the grant of new Awards on the earlier of the 10-year anniversary of the effective date of the 2018 Plan or the 10-year anniversary of the date the 2018 Plan was approved by the board of directors.

Perquisites, Health, Welfare and Retirement Benefits

All of our current named executive officers are eligible to participate in our employee benefit plans, including our medical, dental and vision insurance plans, in each case on the same basis as all of our other employees.

401(k) Plan

We maintain a 401(k) retirement savings plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees may defer eligible compensation on a pre-tax basis, up to the statutorily prescribed annual limits on contributions under the Code. The 401(k) plan provides us with the discretion to match employee contributions**.** During 2017, we made 100% matching contributions on up to 6% of an employee's eligible compensation deferred. These contributions vest in full after an employee has attained six years of service.

Non-Employee Director Compensation

We provide cash and equity-based compensation to our non-employee directors for the time and effort necessary to serve as a member of our board of directors.

Upon the completion of this offering we expect to adopt a non-employee director compensation policy. Under this policy, we will pay each of our non-employee directors a cash retainer for service on the board of directors and for service on each committee on which the director is a member. The chairperson of each committee will receive a higher retainer for such service. These retainers will be payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment will be prorated for any portion of such quarter that the director is not serving on our board of directors. The retainers to be paid to non-employee directors for service on the board of directors and for service on each committee of the board of directors on which the director is a member are expected to be as follows:

Name	Annual Service Retainer	Chairperson Additional Retainer
Board of Directors	$	$
Audit Committee		
Compensation Committee		
Nominating and Corporate Governance Committee		

In addition, under our non-employee director compensation policy to be effective upon the completion of this offering, each non-employee director elected to our board of directors after the completion of this offering are expected to receive an option to purchase shares of our common stock. The shares subject to each such stock option will vest monthly over a three-year period, subject to the director's continued service as a director. Further, on the date of each annual meeting of stockholders held after the completion of this offering, each non-employee director that continues to serve as a non-employee member on our board of directors are expected to receive an option to purchase shares of our common stock. The shares subject to each such stock option will vest in full on the date that is 12 months after the grant date, subject to the director's continued service as a director. The exercise price of these options will equal the fair market value of our common stock on the date of grant.

This policy is intended to provide a total compensation package that enables us to attract and retain qualified and experienced individuals to serve as directors and to align our directors' interests with those of our stockholders.

2017 Director Compensation Table

The following table sets forth in summary form information concerning the compensation that we paid or awarded to our non-executive directors during the fiscal year ended December 31, 2017. Each of Mr. Kendall and Mr. Schobel served on our board of directors during 2017, but did not receive any additional compensation for their service as a director and therefore are not included in the table below. The compensation for Mr. Kendall and Mr. Schobel as an executive officer is set forth above under "—Summary Compensation Table."

Name	Fees Earned or Paid in Cash ($)[1]	Stock Awards[2] ($)	Total ($)
Douglas Bratton	—	—	—
Gregory Brown, M.D.	41,000	—	41,000
John Cochran	—	—	—
Santo Costa	41,000	—	41,000
James S. Scibetta	49,500	—	49,500

(1) These amounts represent fees paid to directors for board meetings and committee meetings. Neither Mr. Bratton nor Mr. Cochran received a fee for their service on our board of directors for the 2017 fiscal year because they represent the Bratton Capital Management Group.

(2) This column reflects the aggregate grant date fair value of the awards granted under the PUP Plans during 2017, calculated in accordance with FASB Accounting Standards Codification Topic 718 Compensation — Stock Compensation ("ASC Topic 718"), and assumes no forfeiture rate derived in the calculation of the grant date fair value of these awards. The assumptions used in calculating the grant date fair value of these awards are set forth in Note 17 to our audited consolidated financial statements included in this prospectus. Because of the contingency of the events that must occur in order for PUP Plan awards to be settled, no compensation expense was recorded because it was not probable at the time of grant that the performance requirements would be met. If, at the time of grant, such performance was probable, the grant date value of the PUP Plan awards granted in 2017 would have been $31,376 for each of Messrs. Bratton, Cochran, Costa and Scibetta and Dr. Brown.

As of December 31, 2017, our non-employee directors held the following number of awards under our PUP Plans:

Non-Employee Director	Number of PUP Plan Awards (#)
Douglas Bratton	926,421
Gregory Brown, M.D.	926,421
John Cochran	926,421
Santo Costa	213,786
James S. Scibetta	71,263

As indicated above, our PUP Plans are expected to be terminated and liquidated in April 2018, effective January 1, 2018. As the result, our non-employee directors are expected to receive the following number of shares of our non-voting common stock and bonus payments (or rights to future bonus payments):

Non-Employee Director	Number of Shares of Non-Voting Common Stock Granted (#)	Additional Payment Amount ($)
Douglas Bratton	926,421	91,407
Gregory Brown, M.D.	926,421	91,407
John Cochran	926,421	91,407
Santo Costa	213,786	21,094
James S. Scibetta	71,263	7,031

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2015 to which we have been a party, in which the amount involved in the transaction exceeded $120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Compensation Discussion and Analysis."

Share Issuances to Employers and Directors

Series A-3 Preferred Interests Issuance

In December 2015, Aquestive, LLC, our parent and predecessor, issued 5,055,000 Series A-3 Preferred Interests to certain investors, including Monoline RXIII, L.P., who purchased 4,950,000 Series A-3 Preferred Interests for $4,950,000. The Series A-3 Preferred Interests contain a conversion option exercisable upon the offering, giving the holder the right to convert the interests into shares of our common stock.

PUP Plans

The PUP Plans of Aquestive, LLC are expected to be terminated in April 2018, effective as of January 1, 2018. Upon termination of the PUP Plans and in lieu of cash, we plan to pay the equivalent value in shares of our common stock. Shares of common stock are expected to be issued to directors, officers and key employees in the following amounts:

Keith J. Kendall	12,338,405
Daniel Barber	1,221,000
Peter Boyd	610,000
John T. Maxwell	1,710,274
A. Mark Schobel	12,338,405
Theresa Wood	978,000
Douglas Bratton	926,421
Gregory Brown, M.D.	926,421
John Cochran	926,426
Santo Costa	213,789
James S. Scibetta	71,263

See "Executive and Director Compensation — Narrative to the Summary Compensation Table — Equity Incentive Plans — PUP Plans" for more information about the PUP Plans.

Employment Arrangements

We have entered into or intend to enter into employment arrangements with our executive officers, as more fully described in "Executive and Director Compensation — Agreements with our Named Executive Officers," "— Incentive Compensation" and "— Potential Payments upon Termination or Change in Control."

Indemnification Agreements

We intend to enter into indemnification agreements with each of our directors and executive officers, in addition to the indemnification provided for in our bylaws and our certificate of incorporation. These agreements, among other things, provide our directors and executive officers with contractual rights to indemnification and, in some cases, expense advancement in any action or proceeding arising out of their services as one of our directors or executive officers or as a director or executive officer of any other company or enterprise to which the person provides services at our request. For more information regarding these agreements, see the section of this prospectus entitled "Executive and Director Compensation — Limitations on liability and indemnification matters."

Policies and Procedures for Transactions with Related Persons

Prior to this offering, we have not had a formal policy regarding approval of transactions with related parties. We expect to adopt a related person transaction policy that will set forth our procedures for the identification, review, consideration and approval or ratification of related person transactions, which will become effective immediately prior to the consummation of this offering. For purposes of our policy only, a “related-person transaction” will be defined as a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any “related person” are participants involving an amount that exceeds $120,000.

Transactions involving compensation for services provided to us as an employee, consultant or director will not be considered related-person transactions under this policy. A related person will be defined as any executive officer, director or a holder of more than 5% of our common stock, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our audit committee (or, where review by our audit committee would be inappropriate, to another independent body of our board of directors) for review. The presentation must include a description of, among other things, the material facts, the direct and indirect interests of the related persons, the benefits of the transaction to us and whether any alternative transactions are available. To identify related-person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-person transactions, our audit committee or other independent body of our board of directors will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director’s independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from our employees generally.

The policy will require that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion. In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval.

All of the transactions described above were entered into prior to the adoption of the written policy.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our capital stock by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our named executive officers and key employees; and
- all of our current executive officers and directors as a group.

The number of shares beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of _____, 2018 through the exercise of any stock options or other rights. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by that person.

The table below does not give effect to the potential purchases by such stockholders in this offering.

The percentage of shares beneficially owned before the offering is computed on the basis of shares of our common stock outstanding as of , 2018. The percentage of shares beneficially owned after the offering is computed on the basis of shares of our common stock outstanding as of , 2018 which reflects shares of our common stock sold in the offering.

Except as otherwise noted below, the address for each person or entity listed in the table is c/o Aquestive Therapeutics, Inc., 30 Technology Drive, Warren, NJ 07059.

The percentages depicted in the table below account for the distribution of our shares held by Aquestive Partners, LLC to the holders of interests in Aquestive Partners, LLC.

	Shares Beneficially Owned			
	Prior to the Offering		After the Offering	
	Number	%	Number	%
Five percent stockholders:				
		%		%
		%		%
		%		%
		%		%
		%		%
Directors, executive officers and key employees:				
Keith J. Kendall		%		%
Daniel Barber		%		%
Peter Boyd		%		%
John T. Maxwell		%		%
A. Mark Schobel		%		%
Theresa Wood		%		%
Douglas Bratton		%		%
Gregory Brown, M.D.		%		%
John Cochran		%		%
Santo Costa		%		%
James S. Scibetta		%		%
All directors executive officers and key employees as a group (11 persons)		%		%

* *Represents beneficial ownership of less than 1%.*

DESCRIPTION OF CAPITAL STOCK

The following descriptions are summaries of the material terms of our restated certificate of incorporation and amended and restated bylaws, which will be effective upon consummation of this offering. The descriptions of the common stock and preferred stock give effect to changes to our capital structure that will occur immediately prior to the closing of this offering. We refer in this section to our restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.

General

Upon the closing of this offering and the filing of our certificate of incorporation, our authorized capital stock will consist of 250,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of preferred stock, par value $0.001 per share. All of our authorized preferred stock upon the closing of this offering will be undesignated. The following is a summary of the rights of our common and preferred stock and some of the provisions of our certificate of incorporation and bylaws, which will become effective upon the closing of this offering and of the Delaware General Corporation Law. This summary is not complete. For more detailed information, please see our certificate of incorporation and bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the Delaware General Corporation Law.

Common Stock

Outstanding Shares

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by the board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders. The affirmative vote of holders of at least $66^{2/3}\%$ of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our certificate of incorporation, including provisions relating to amending our bylaws, the classified board, the size of our board, removal of directors, director liability, vacancies on our board, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction, provided, however, that this restriction shall not apply to, and such $66^{2/3}\%$ vote shall not be required for, any such amendment, change or repeal approved by the affirmative vote of at least a majority of the then current duly elected board of directors, in which case such action shall require only the vote of shareholders as required under Delaware law.

Dividends

Subject to preferences that may apply to any outstanding preferred stock, holders of our common stock are entitled to receive ratably any dividends that our board of directors may declare out of funds legally available for that purpose on a non-cumulative basis.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and

privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Preferred Stock

As of , we had shares of preferred stock outstanding, held of record by stockholders. Immediately after the consummation of this offering, our certificate of incorporation will be amended and restated to remove all references to such shares of preferred stock. Under our amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Options and Warrants

As of December 31, 2017, we had granted no options to any of our directors or officers. For additional information regarding terms of our equity incentive plan and future grants to be made thereunder, see the section titled “Executive and Director Compensation — 2018 Equity Incentive Plan.”

In connection with the Loan Agreement, on August 16, 2016 we issued to Perceptive 11,625,437 warrants to purchase shares of our common stock representing 4.5% of our fully diluted common stock on an as converted basis at an exercise price of $0.01 per interest. The warrants expire on August 16, 2023 and are subject to anti-dilution adjustments so that, upon exercise, they will represent 4.5% of our fully diluted common stock on an as converted basis.

Registration Rights

Series A-2 Registration Rights

We granted registration rights to holders of our Series A-2 Preferred Interests with respect to the shares of common equity issuable upon conversion of the Series A-2 Preferred Interests we issued in July 2008. Upon consummation of this offering, the holders of Series A-2 Preferred Interests will receive shares of our common stock in exchange for their Series A-2 Preferred Interests, or the A-2 Exchange. Pursuant to the terms of the Limited Liability Company Agreement of Aquestive Partners, LLC, or the LLC Agreement, following the A-2 Exchange, the holders of 82,071,200 shares of our common stock, or the Series A-2 Registrable Securities, will continue to be entitled to rights with respect to the registration of the Series A-2 Registrable Securities under the Securities Act, as described below. However, the holders of a majority of the Series A-2 Preferred Interests have waived all registration rights with respect to the Series A-2 Preferred Interests in connection with this offering.

Demand Registration Rights

Holders of at least 40% of the Series A-2 Registrable Securities then outstanding can request that we register all or part of their securities on Form S-1 and holders of at least 50% of the Series A-2 Registrable Securities then outstanding can request that we register all or part of their securities on Form S-3 if we are eligible to file a registration statement on Form S-3 and if the aggregate price to the public of the Series A-2 Registrable Securities offered, net of underwriting discounts and commissions, is at least $20,000,000. We and the underwriters of any underwritten offering will have the right to limit the

number of shares registered by these holders if they determine that marketing factors require limitation, in which case the number of shares to be registered will be apportioned pro rata among these holders, according to the total amount of Series A-2 Registrable Securities entitled to be included by each holder.

"Piggyback" Registration Rights

If we register any of our securities for public sale in another offering, holders of Series A-2 Registrable Securities will have the right to include their shares in the registration statement. However, this right does not apply to the registration relating to employee benefit plans or a registration relating solely to a transaction under Rule 144 of the Securities Act. We shall not be required to complete a Form S-3 if the holders of the Series A-2 Registrable Securities have had the opportunity to participate in two or more piggyback registrations in the preceding 12-month period. We and the underwriters of any underwritten offering will have the right to limit the number of shares registered by these holders if they determine that marketing factors require limitation, in which case the number of shares to be registered will be apportioned pro rata among these holders, according to the total amount of Series A-2 Registrable Securities entitled to be included by each holder.

Expenses of Registration

We generally will pay all expenses related to the registrations, other than sales commissions, stock transfer taxes, underwriting discounts and the fees and disbursements of counsel for the selling security holders.

Expiration of Registration Rights

The registration rights for the Series A-2 Registrable Securities granted under the LLC Agreement will terminate on July 31, 2018.

Series A-3 Registration Rights

We granted registration rights to holders of our Series A-3 Preferred Interests with respect to the shares of common equity issuable upon conversion of the Series A-3 Preferred Interests we issued in December 2015. Upon consummation of this offering, the holders of Series A-3 Preferred Interests will receive shares of our common stock in exchange for their Series A-3 Preferred Interests, or the A-3 Exchange. Pursuant to the terms of the LLC Agreement, following the A-3 Exchange, the holders of 5,055,000 shares of our common stock, or the Series A-3 Registrable Securities, will be entitled to rights with respect to the registration of the Series A-3 Registrable Securities under the Securities Act, as described below. However, the holders of a majority of the Series A-3 Preferred Interests have waived all registration rights with respect to the Series A-3 Preferred Interests in connection with this offering.

Demand Registration Rights

Beginning 180 days after the consummation of this offering, holders of at least 40% of the Series A-3 Registrable Securities then outstanding can request that we register all or part of their securities on Form S-1 and holders of at least 50% of the Series A-3 Registrable Securities then outstanding can request that we register all or part of their securities on Form S-3 if we are eligible to file a registration statement on Form S-3 and if the aggregate price to the public of the registrable securities offered, net of underwriting discounts and commissions, is at least $5,000,000. We and the underwriters of any underwritten offering will have the right to limit the number of shares registered by these holders if they determine that marketing factors require limitation, in which case the number of shares to be registered will be apportioned pro rata among these holders, according to the total amount of Series A-3 Registrable Securities entitled to be included by each holder.

"Piggyback" Registration Rights

If we register any of our securities for public sale in another offering, holders of Series A-3 Registrable Securities will have the right to include their shares in the registration statement. However, this right does not apply to a registration relating to employee benefit plans or a registration relating solely to a transaction under Rule 144 of the Securities Act. We shall not be required to complete a Form S-3 if

the holders of the Series A-3 Registrable Securities have had the opportunity to participate in two or more piggyback registrations in the preceding 12-month period. We and the underwriters of any underwritten offering will have the right to limit the number of shares registered by these holders if they determine that marketing factors require limitation, in which case the number of shares to be registered will be apportioned pro rata among these holders, according to the total amount of Series A-3 Registrable Securities entitled to be included by each holder.

Expenses of Registration

We generally will pay all expenses related to the registrations, other than sales commissions, stock transfer taxes, underwriting discounts and the fees and disbursements of counsel for the selling security holders.

Anti-Takeover Effects of Provisions of Our Certificate of Incorporation and Our Bylaws

Our certificate of incorporation and bylaws will contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of the board of directors and which may have the effect of delaying, deferring or preventing a future takeover or change in control of the company unless such takeover or change in control is approved by the board of directors.

These provisions include:

Classified Board. Our certificate of incorporation will provide that our board of directors will be divided into three classes of directors, with the classes as nearly equal in number as possible. As a result, approximately one-third of our board of directors will be elected each year. The classification of directors will have the effect of making it more difficult for stockholders to change the composition of our board. Our certificate of incorporation will also provide that, subject to any rights of holders of preferred stock to elect additional directors under specified circumstances, the number of directors will be fixed exclusively pursuant to a resolution adopted by our board of directors. Upon consummation of this offering, we expect that our board of directors will have seven members.

Action by Written Consent; Special Meetings of Stockholders. Our certificate of incorporation will provide that stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. Our certificate of incorporation and the bylaws will also provide that, except as otherwise required by law, special meetings of the stockholders can be called only by or at the direction of the board of directors pursuant to a resolution adopted by a majority of the total number of directors. Stockholders will not be permitted to call a special meeting or to require the board of directors to call a special meeting.

Removal of Directors. Our certificate of incorporation will provide that our directors may be removed only for cause by the affirmative vote of at least $66^{2/3}\%$ of the votes that all our stockholders would be entitled to cast in an annual election of directors, voting together as a single class, at a meeting of the stockholders called for that purpose. This requirement of a supermajority vote to remove directors could enable a minority of our stockholders to prevent a change in the composition of our board.

Advance Notice Procedures. Our bylaws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the bylaws will not give the board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the company.

Super Majority Approval Requirements. The Delaware General Corporation Law generally provides that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless either a corporation's certificate of incorporation or bylaws requires a greater percentage. A majority vote of our board of directors or the affirmative vote of holders of at least $66^{2/3}$% of the total votes of the outstanding shares of our capital stock entitled to vote with respect thereto, voting together as a single class, will be required to amend, alter, change or repeal the bylaws. In addition, the affirmative vote of the holders of at least $66^{2/3}$% of the total votes of the outstanding shares of our capital stock entitled to vote with respect thereto, voting together as a single class, will be required to amend, alter, change or repeal, or to adopt any provisions inconsistent with, any of the provisions in our certificate of incorporation relating to amendments to our certificate of incorporation and bylaws and as described under "Action by Written Consent; Special Meetings of Stockholders", "Classified Board" and "Removal of Directors" above. This requirement of a supermajority vote to approve amendments to our bylaws and certificate of incorporation could enable a minority of our stockholders to exercise veto power over any such amendments.

Authorized but Unissued Shares. Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital and corporate acquisitions. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of us or our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Exclusive Forum. Our certificate of incorporation will provide that, subject to limited exceptions, the state or federal courts located in the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (iv) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our certificate of incorporation described above. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with one or more actions or proceedings described above, a court could find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable.

Section 203 of the Delaware General Corporation Law

Upon consummation of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law, or Section 203. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among

other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An “interested stockholder” is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation’s voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 75% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may “opt out” of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders’ amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Nasdaq Listing

We intend to apply for listing of our common stock on the Nasdaq Global Market under the symbol “AQST.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of common stock in the public market could adversely affect prevailing market prices. Furthermore, since only a limited number of shares will be available for sale shortly after this offering because of contractual and legal restrictions on resale described below, sales of substantial amounts of common stock in the public market after the restrictions lapse could adversely affect the prevailing market price for our common stock as well as our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of December 31, 2017, upon the closing of this offering, shares of common stock will be outstanding, assuming no exercise of the underwriters' option to purchase additional shares. All of the shares sold in this offering will be freely tradable unless purchased by our "affiliates" as that term is defined in Rule 144 under the Securities Act or purchased by existing stockholders and their affiliated entities that are subject to lock-up agreements. Except as set forth below, the remaining shares of common stock outstanding after this offering will be restricted as a result of securities laws and lock-up agreements with us and/or the underwriters. These remaining shares will generally become available for sale in the public market as follows:

Approximate Number of Shares	First Date Available for Sale into Public Market
shares	181 days after the date of this prospectus, upon expiration of the lock-up agreements referred to below, subject in some cases to applicable volume, manner of sale and other limitations under Rule 144 and Rule 701.

We may issue shares of common stock from time to time as consideration for future acquisitions, investments or other corporate purposes. In the event that any such acquisition, investment or other transaction is significant, the number of shares of common stock that we may issue may in turn be significant. We may also grant registration rights covering those shares of common stock issued in connection with any such acquisition and investment.

Rule 144

In general, under Rule 144 as currently in effect, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, any person who is not an affiliate of ours and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell shares without restriction, provided current public information about us is available. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available. Beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of restricted shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; or
- the average weekly trading volume of our common stock on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales of restricted shares under Rule 144 held by our affiliates are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144 also provides that affiliates relying on Rule 144 to sell shares of our common stock that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted shares have entered into lock-up agreements as described below and their restricted shares will become eligible for sale at the expiration of the restrictions set forth in those agreements.

Rule 701

Under Rule 701, shares of our common stock acquired upon the exercise of currently outstanding options or pursuant to other rights granted under our stock plans may be resold by:

- persons other than affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject only to the manner-of-sale provisions of Rule 144; and
- our affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject to the manner-of-sale and volume limitations, current public information and filing requirements of Rule 144, in each case, without compliance with the six-month holding period requirement of Rule 144.

Lock-Up Agreements

We, along with our directors, executive officers and substantially all of our other stockholders and option holders, have agreed that for a period of 180 days after the date of this prospectus, subject to specified exceptions, we or they will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock without the consent of BMO Capital Markets Corp. and RBC Capital Markets, LLC. Upon expiration of the “lock-up” period, certain of our stockholders will have the right to require us to register their shares under the Securities Act. See “Registration Rights” below.

After this offering, certain of our employees, including our executive officers and/or directors, may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements described above.

Registration Rights

Upon consummation of this offering, the holders of 87,126,200 shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up arrangement described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates, immediately upon the effectiveness of such registration statement. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. See “Description of Capital Stock — Registration Rights.”

Equity Incentive Plans

We intend to file with the SEC a registration statement on Form S-8 under the Securities Act covering the shares of common stock subject to stock awards outstanding or reserved for issuance under the 2018 Plan. The registration statement is expected to be filed and become effective as soon as practicable after the closing of this offering. Accordingly, shares registered under the registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following discussion is a general summary of the material U.S. federal income tax considerations related to the acquisition, ownership and disposition of our common stock to Non-U.S. Holders as of the date hereof.

For the purposes of this discussion, a "Non-U.S. Holder" of our common stock means a holder that is not a U.S. person or an entity treated as a partnership for U.S. federal income tax purposes. The term U.S. person means:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation) created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

This summary is not intended to be a complete analysis of all the U.S. federal income tax considerations that may be relevant to Non-U.S. Holders. This summary does not consider specific facts and circumstances that may be relevant to a particular Non-U.S. Holder's tax particular circumstances and does not consider the state, local or non-U.S. tax consequences of an investment in our common stock. It also does not consider Non-U.S. Holders subject to special tax treatment under U.S. federal income tax laws (including partnerships or other pass-through entities, banks and insurance companies, regulated investment companies, real estate investment trusts, dealers in securities, controlled entities of foreign sovereigns, holders of our common stock held as part of a "straddle," "hedge," "conversion transaction" or other risk-reduction transaction, controlled foreign corporations, passive foreign investment companies, companies that accumulate earnings to avoid U.S. federal income tax, foreign tax-exempt organizations, "expatriated entities," companies subject to the "stapled stock" rules, persons that own or are deemed to own more than 5% of our capital stock, former U.S. citizens or residents and persons who hold or receive the shares of common stock as compensation). This summary is based on provisions of the Internal Revenue Code of 1986, as amended, or the Code, applicable Treasury regulations, administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, and judicial decisions, all as in effect on the date hereof, and all of which are subject to change, possibly on a retroactive basis, and different interpretations.

This summary is general information only. It is not tax advice. We urge each prospective Non-U.S. Holder to consult their own tax advisor concerning the particular U.S. federal, state, local and non-U.S. income, estate and other tax consequences of the purchase, ownership and disposition of our common stock.

U.S. Trade or Business Income

For purposes of this discussion, dividend income and gain on the sale or other taxable disposition of shares of our common stock will be considered to be "U.S. trade or business income" if such dividend income or gain is (1) effectively connected with the conduct by a Non-U.S. Holder of a trade or business within the United States; and (2) in the case of a Non-U.S. Holder that is eligible for the benefits of an income tax treaty with the United States, attributable to a "permanent establishment" or "fixed base" maintained by the Non-U.S. Holder in the United States. Generally, U.S. trade or business income is not subject to U.S. federal withholding tax (provided the Non-U.S. Holder complies with applicable certification and disclosure requirements); instead, U.S. trade or business income is subject to U.S. federal income tax on a net income basis at regular U.S. federal income tax rates in the same manner as if the recipient were a U.S. person. Any U.S. trade or business income received by a Non-U.S. Holder that is treated as a corporation also may be subject to a "branch profits tax" at a 30% rate, or such lower rate as provided under an applicable income tax treaty.

Distributions

Distributions of cash or property (other than certain stock distributions) that we pay with respect to our common stock (or certain redemptions that are treated as distributions with respect to our shares of common stock) will be taxable as dividends for U.S. federal income tax purposes to the extent paid out of our current or accumulated earnings and profits as determined for U.S. federal income tax purposes. Subject to the discussion in "—Foreign Account Tax Compliance Act (FATCA)" below, a Non-U.S. Holder generally will be subject to withholding of U.S. federal income tax at a rate of 30% of the gross amount of our distributions taxable as dividends or such lower rate as may be specified by an applicable income tax treaty. In order to obtain a reduced rate of U.S. federal withholding tax under an applicable income tax treaty, a Non-U.S. Holder will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or appropriate substitute or successor form) certifying its entitlement to benefits under the treaty. A Non-U.S. Holder of our common stock that is eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for refund with the IRS. A Non-U.S. Holder is encouraged to consult its own tax advisor regarding its possible entitlement to benefits under an income tax treaty. If the amount of a distribution exceeds our current and accumulated earnings and profits, such excess first will be treated as a tax-free return of capital to the extent of the Non-U.S. Holder's adjusted tax basis in our shares, and thereafter will be treated as capital gain. A Non-U.S. Holder's adjusted tax basis in our shares will generally be equal to the amount the Non-U.S. Holder paid for its shares, reduced by the amount of any distributions treated as a return of capital. See, "—Sale, Exchange or Other Disposition of Our Common Stock" below.

The U.S. federal withholding tax does not apply to dividends that are U.S. trade or business income, as described above, of a Non-U.S. Holder who provides a properly executed IRS Form W-8ECI (or appropriate substitute or successor form), certifying that the dividends are subject to tax as income effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Sale, Exchange or Other Disposition of Our Common Stock

Subject to the discussion in "—Foreign Account Tax Compliance Act (FATCA)" below, a Non-U.S. Holder generally will not be subject to U.S. federal income tax or withholding tax in respect of any gain recognized on a sale, exchange or other disposition of shares of our common stock unless:

- the gain is U.S. trade or business income, as described above;
- if a Non-U.S. Holder is an individual and holds shares of our common stock as a capital asset, the Non-U.S. Holder is present in the United States for 183 or more days in the taxable year of the sale or other disposition but is not treated as a resident of the United States for that year, and certain other conditions are met; or
- we are or have been during a specified testing period a "United States real property holding corporation" for U.S. federal income tax purposes.

Gain described in the first bullet above will be subject to U.S. federal income tax in the manner described under "—U.S. Trade or Business Income." Gain described in the second bullet above will be subject to a flat 30% tax (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S. source capital losses (even though the Non-U.S. Holder is not considered a resident of the United States), provided that the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

In general, a corporation is a "United States real property holding corporation" if the fair market value of its "U.S. real property interests" equals or exceeds 50% of the sum of the fair market value of its worldwide (domestic and foreign) real property interests and its other assets used or held for use in a trade or business. Although there can be no assurance, we believe that we have not been, and we are not and do not anticipate becoming, a "United States real property holding corporation" for U.S. federal income tax purposes. If we are or become a "United States real property holding corporation," a Non-U.S. Holder, nevertheless, will not be subject to U.S. federal income or withholding tax in respect of any gain on a sale or other disposition of our common stock so long as shares of our common stock are "regularly traded on an established securities market" as defined under applicable Treasury regulations and a

Non-U.S. Holder owns, actually or constructively, 5% or less of our shares at all times during the shorter of the five-year period ending on the date of disposition and such Non-U.S. Holder's holding period for our shares. If we are a United States real property holding corporation and either our common stock is not regularly traded on an established securities market or a Non-U.S. Holder holds, or is treated as holding, more than 5% of our outstanding common stock, directly or indirectly, during the applicable testing period, any gain recognized by such Non-U.S. Holder will generally be subject to U.S. federal income tax rates in the same manner as if the Non-U.S. Holder were a resident of the United States. If we are a U.S. real property holding corporation and our common stock is not regularly traded on an established securities market, such Non-U.S. Holder's proceeds received on the disposition of shares will also generally be subject to withholding at a rate of 15%. Prospective investors should be aware that no assurance can be given that our shares will be so regularly traded when a Non-U.S. Holder sells its shares of our common stock.

Information Reporting Requirements and Backup Withholding

We must annually report to the IRS and to each Non-U.S. Holder any dividend income that is subject to U.S. federal withholding tax, or that is exempt from such withholding tax pursuant to an income tax treaty with the United States. Copies of these information returns also may be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides. Under certain circumstances, the Code imposes a backup withholding obligation on certain reportable payments. Dividends paid to a Non-U.S. Holder of our common stock generally will be exempt from backup withholding if the Non-U.S. Holder provides a properly executed IRS Form W-8BEN or W-8BEN-E (or other applicable form) or otherwise establishes an exemption.

The payment of the proceeds from the disposition of our common stock to or though the U.S. office of any broker, U.S. or foreign, will be subject to information reporting and possible backup withholding unless the owner certifies (usually on IRS Form W-8BEN or W-8BEN-E) as to its non-U.S. status under penalties of perjury or otherwise establishes an exemption, provided that the broker does not have actual knowledge or reason to know that the holder is a U.S. person or that the conditions of any other exemption are not, in fact, satisfied. The payment of the proceeds from the disposition of our common stock to or through a non-U.S. office of a non-U.S. broker will not be subject to information reporting or backup withholding unless the non-U.S. broker has certain types of relationships with the United States (which we refer to as a United States related person). In the case of the payment of the proceeds from the disposition of our common stock to or through a non-U.S. office of a broker that is either a U.S. person or a United States related person, the Treasury Regulations require information reporting (but not the backup withholding) on the payment unless the broker has documentary evidence in its files that the owner is a non-U.S. Holder and the broker has no knowledge to the contrary. Non-U.S. Holders should consult their own tax advisors on the application of information reporting and backup withholding to them in their particular circumstances (including upon their disposition of our common stock).

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a Non-U.S. Holder will be credited against the Non-U.S. Holder's U.S. federal income tax liability, if any, with any excess withholding refunded to the Non-US. Holder, provided that the required information is furnished on a timely basis to the IRS.

Foreign Account Tax Compliance Act (FATCA)

Pursuant to sections 1471 through 1474 of the Code, commonly known as the Foreign Account Tax Compliance Act, or FATCA, withholding taxes may apply to certain types of payments made to "foreign financial institutions" (as specifically defined in the Code) and certain other non-United States entities. Specifically, a 30% withholding tax may be imposed on dividends and gross proceeds from the sale, exchange or other disposition of our common stock paid to a foreign financial institution or to a non-financial foreign entity unless (i) the foreign financial institution undertakes certain diligence and reporting, (ii) the non-financial foreign entity either certifies it does not have any substantial United States owners or furnishes identifying information regarding each substantial United States owner or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in clause (i) above, it may be required to enter into an agreement with the IRS requiring,

among other things, that it undertake to identify accounts held by certain United States persons or United States-owned foreign entities, annually report certain information about such accounts, and withhold 30% on payments to non-compliant foreign financial institutions and certain other account holders or may be required to comply with reporting and other compliance obligations under an intergovernmental agreement between their country of organization and the U.S. Treasury. The withholding provisions above currently applies to payments of dividends and will generally apply to payments of gross proceeds from the sale or disposition of stock on or after January 1, 2019. A Non-U.S. Holder that is not subject to FATCA withholding generally may certify its exempt status by furnishing a properly executed IRS Form W-8BEN or Form W-8BEN-E (or other appropriate form), as applicable. Under certain circumstances, a non-U.S. Holder may be eligible for refunds or credits of the tax. Non-U.S. Holders are urged to consult their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

THE PRECEDING DISCUSSION OF U.S. FEDERAL INCOME TAX CONSIDERATIONS IS FOR GENERAL INFORMATION ONLY. IT IS NOT TAX ADVICE. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAW.

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement, dated the date of this prospectus, with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the respective number of shares of common stock shown opposite its name in the following table. BMO Capital Markets Corp. and RBC Capital Markets, LLC are the representatives of the underwriters.

Underwriters	Number of Shares
BMO Capital Markets Corp.	
RBC Capital Markets, LLC	
Wedbush Securities Inc.	
JMP Securities LLC	
Total	

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until that option is exercised. If an underwriter fails or refuses to purchase any of its committed shares, the purchase commitments of the non-defaulting underwriters may be increased or the offering may be terminated.

The underwriters have an option to buy up to an additional shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise this option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above, and the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriters propose to offer the shares of our common stock directly to the public at the initial public offering price set forth on the cover of this prospectus and to certain dealers at such offering price less a concession not in excess of $ per share. After the initial public offering of the shares, the offering price and the selling concession may be changed by the underwriters.

The following table shows the per share and total underwriting discounts and commissions to be paid by us to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	No Exercise	Full Exercise
Per Share	$	$
Total	$	$

We estimate that the total expenses of the offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding underwriting discounts and commissions, will be approximately $, all of which will be paid by us. We have agreed to reimburse the underwriters for certain of their expenses incurred in connection with the clearance of this offering with the Financial Industry Regulatory Authority, Inc.

We and our officers and directors and the holders of substantially all of our capital stock and options have agreed with the underwriters that, for a period of 180 days after the date of this prospectus, subject to certain exceptions, we and they will not (i) offer, sell, pledge, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of (or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition), directly or indirectly, including the filing (or participation in the filing) with the SEC of a registration statement under the Securities Act to register, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock or warrants or other rights to acquire shares of our common stock of which such officer, director or holder is now, or may in the future become, the beneficial owner (within the meaning of Rule 13d-3 under the Exchange Act), or (ii) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, directly or indirectly, any of the economic benefits or risks of ownership of such common

stock, securities, warrants or other rights to acquire common stock, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of common stock or other securities, in cash or otherwise, or (3) publicly disclose the intention to enter into any transaction described in clause (i) or (ii) above, except with the prior written consent of BMO Capital Markets Corp. and RBC Capital Markets, LLC; provided that BMO Capital Markets Corp. and RBC Capital Markets, LLC, on behalf of the underwriters, have agreed to notify us at least three business days before the effective date of any release or waiver granted to one of our officers or directors, and we have agreed to announce the impending release or waiver by issuing a press release through a major news service at least two business days before the effective date of the release or waiver.

The restrictions above do not apply to transfers of securities as a bona fide gift, subject to certain limitations set forth in the lock-up agreements.

See “Shares Eligible for Future Sale” for a discussion of certain transfer restrictions.

Prior to the offering, there has been no public market for our common stock. The initial public offering price will be negotiated among us and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be our historical performance, estimates of our business potential and earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

We intend to apply to have our common stock listed on the Nasdaq Global Market under the symbol “AQST.” In connection with the offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A “covered short position” is a short position that is not greater than the amount of additional shares for which the underwriters’ option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. “Naked” short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the consummation of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the common stock. As a result, the price of our common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on the Nasdaq Global Market, in the over-the-counter market or otherwise.

In connection with this offering, the underwriters may engage in passive market making transactions in the common stock on the Nasdaq Global Market in accordance with Rule 103 of Regulation M under the Exchange Act during a period before the commencement of offers or sales of common stock and extending through the completion of distribution. A passive market maker must display its bid at a price

not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded. Passive market making may cause the price of our common stock to be higher than the price that otherwise would exist in the open market in the absence of those transactions. The underwriters are not required to engage in passive market making and may end passive market making activities at any time.

The underwriters do not expect sales to discretionary accounts to exceed five percent of the total number of shares offered.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act and to contribute to payments that the underwriters may be required to make for these liabilities.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of our common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to us and to persons and entities with relationships with us, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to our assets, securities and/or instruments (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with us. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

Offer Restrictions Outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Australia

No prospectus or other disclosure document, as defined in the Corporations Act 2001 (Cth) of Australia, or Corporations Act, in relation to our securities has been or will be lodged with the Australian Securities & Investments Commission, or ASIC. This document has not been lodged with ASIC and is only directed to certain categories of exempt persons. Accordingly, if you receive this document in Australia:

(a) you confirm and warrant that you are either:

(i) a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;

(ii) a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to us which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;

(iii) a person associated with the company under section 708(12) of the Corporations Act; or

(iv) a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act, and to the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act, any offer made to you under this document is void and incapable of acceptance; and

(b) you warrant and agree that you will not offer any of our securities for resale in Australia within 12 months of that security being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

Canada

The common stock may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the common stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts*, or NI 33-105, the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

China

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

European Economic Area

Any distributor subject to MiFID II that is offering, selling or recommending the securities is responsible for undertaking its own target market assessment in respect of the securities and determining its own distribution channels for the purposes of the MiFID product governance rules under Commission

Delegated Directive (EU) 2017/593, or Delegated Directive. Neither the issuer nor the underwriters make any representations or warranties as to a distributor's compliance with the Delegated Directive.

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive, or, each, a relevant member state, with effect from and including the date on which the Prospectus Directive is implemented in that relevant member state (the relevant implementation date), an offer of securities described in this prospectus may not be made to the public in that relevant member state other than:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100 or, if the relevant member state has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the relevant Dealer or Dealers nominated by us for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive;

provided that no such offer of securities shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

For purposes of this provision, the expression an "offer of securities to the public" in any relevant member state means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the expression may be varied in that member state by any measure implementing the Prospectus Directive in that member state, and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the relevant member state) and includes any relevant implementing measure in the relevant member state. The expression 2010 PD Amending Directive means Directive 2010/73/EU.

The sellers of the securities have not authorized and do not authorize the making of any offer of securities through any financial intermediary on their behalf, other than offers made by the underwriters with a view to the final placement of the securities as contemplated in this prospectus. Accordingly, no purchaser of the securities, other than the underwriters, is authorized to make any further offer of the securities on behalf of the sellers or the underwriters.

France

Neither this prospectus nor any other offering material relating to the securities described in this prospectus has been submitted to the clearance procedures of the *Autorité des Marchés Financiers* or of the competent authority of another member state of the European Economic Area and notified to the *Autorité des Marchés Financiers*. The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering material relating to the securities has been or will be:

- released, issued, distributed or caused to be released, issued or distributed to the public in France; or
- used in connection with any offer for subscription or sale of the securities to the public in France.

Such offers, sales and distributions will be made in France only:

- to qualified investors (*investisseurs qualifiés*) and/or to a restricted circle of investors (*cercle restreint d'investisseurs*), in each case investing for their own account, all as defined in, and in accordance with articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French *Code monétaire et financier*;
- to investment services providers authorized to engage in portfolio management on behalf of third parties; or

- in a transaction that, in accordance with article L.411-2-II-1° -or-2° -or 3° of the French *Code monétaire et financier* and article 211-2 of the General Regulations (*Règlement Général*) of the *Autorité des Marchés Financiers*, does not constitute a public offer (*appel public à l'épargne*).

The securities may be resold directly or indirectly, only in compliance with articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French *Code monétaire et financier*.

Hong Kong

The securities may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to the securities may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to the securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

Ireland

The information in this document does not constitute a prospectus under any Irish laws or regulations, and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005, or the Prospectus Regulations. The common stock has not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(l) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

Israel

The common stock offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority, or the ISA, nor have such common stock been registered for sale in Israel. The shares and warrants may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with the offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the common stock being offered. Any resale in Israel, directly or indirectly, to the public of the common stock offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

Italy

The offering of the common stock in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Società e la Borsa), the "CONSOB," pursuant to the Italian securities legislation and, accordingly, no offering material relating to the common stock may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998, or Decree No. 58, other than:

- to Italian qualified investors, as defined in Article 100 of Decree No. 58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999, or Regulation No. 1197l, as amended, or the Qualified Investors; and
- in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the common stock or distribution of any offer document relating to the common stock in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

- made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and
- in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Any subsequent distribution of the common stock in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such common stock being declared null and void and in the liability of the entity transferring the common stock for any damages suffered by the investors.

Japan

The securities offered in this prospectus have not been and will not be registered under the Financial Instruments and Exchange Law of Japan. The securities have not been offered or sold and will not be offered or sold, directly or indirectly, in Japan or to or for the account of any resident of Japan (including any corporation or other entity organized under the laws of Japan), except (i) pursuant to an exemption from the registration requirements of the Financial Instruments and Exchange Law and (ii) in compliance with any other applicable requirements of Japanese law.

Portugal

This document is not being distributed in the context of a public offer of financial securities (oferta púbica de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The common stock has not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the common stock has not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of common stock in Portugal are limited to persons who are “qualified investors” (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the securities may not be circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to compliance with conditions set forth in the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant party which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the securities pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such securities of that corporation or such rights and interest in that trust are acquired at a consideration of not less than $200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;
- where no consideration is or will be given for the transfer; or
- where the transfer is by operation of law.

Sweden

This document has not been, and will not be, registered with or approved by Finansinspektionen, or the Swedish Financial Supervisory Authority. Accordingly, this document may not be made available, nor may the common stock be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of common stock in Sweden is limited to persons who are "qualified investors" (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Switzerland

The common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the common stock may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the common stock has been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of common stock will not be supervised by, the Swiss Financial Market Supervisory Authority (FINMA).

This document is personal to the recipient only and not for general circulation in Switzerland.

United Arab Emirates

Neither this document nor the common stock have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor have we received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the common stock within the United Arab Emirates. This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the common stock, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the United Arab Emirates by us.

No offer or invitation to subscribe for common stock is valid or permitted in the Dubai International Financial Centre.

United Kingdom

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of Section 85 of the Financial Services and Markets Act 2000, as amended, or the FSMA) has been published or is intended to be published in respect of the common stock. This document is issued on a confidential basis to "qualified investors" (within the meaning of Section 86(7) of FSMA) in the United Kingdom, and the common stock may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances that do not require the publication of a prospectus pursuant to Section 86(1) FSMA. This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of Section 21 of FSMA) received in connection with the issue or sale of the common stock has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which Section 21(1) of FSMA does not apply to us.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005, or the FPO, (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated, or, together, relevant persons. The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a United Kingdom relevant person should not act or rely on this document or any of its contents.

LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Dechert LLP, New York, New York. Certain legal matters relating to this offering will be passed upon for the underwriters by Cooley LLP, New York, New York.

EXPERTS

The consolidated financial statements of MonoSol Rx, LLC, as of December 31, 2017 and 2016, and for each of the years in the two-year period ended December 31, 2017, have been included herein and in the registrants statement appearing elsewhere herein, and in reliance upon the report of KPMG LLP, an independent registered public accounting firm, upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. You may also request a copy of these filings, at no cost, by writing us at 30 Technology Drive, Warren, New Jersey 07059 or telephoning us (908) 941-1900.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and web site of the SEC referred to above. We also maintain a website at www.aquestive.com, at which, following the closing of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is incorporated by reference in, and is not part of, this prospectus.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

MonoSol Rx, LLC

Report of Independent Registered Public Accounting Firm

To the Members and Board of Directors
MonoSol Rx, LLC:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of MonoSol Rx, LLC and its subsidiary (the "Company") as of December 31, 2017 and 2016, the related consolidated statements of operations and comprehensive loss, changes in members' deficit, and cash flows for each of the years in the two-year period ended December 31, 2017, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2006.

New York, New York
April 2, 2018

MonoSol Rx, LLC
Consolidated Balance Sheets
(In thousands, except unit amounts)

	December 31, 2017	December 31, 2016	Pro Forma December 31, 2017 (Note 2(D)) (Unaudited)
Assets			
Current assets:			
Cash and cash equivalents	$ 17,379	$ 9,209	$ 17,379
Trade and other receivables, net	6,179	10,817	6,179
Inventories	4,014	2,886	4,014
Prepaid expenses and other current assets	591	420	591
Total current assets	28,163	23,332	28,163
Property and equipment, net	13,460	15,122	13,460
Intangible assets, net	254	305	254
Other assets	1,239	630	1,239
Total assets	$ 43,116	$ 39,389	$ 43,116
Liabilities and Members' Deficit			
Current liabilities:			
Accounts payable	$ 9,601	$ 6,638	$ 9,601
Accrued expenses	4,402	3,366	4,402
Deferred revenue	1,347	802	1,347
Total current liabilities	15,350	10,806	15,350
Noncurrent liabilities:			
Loans payable, net	45,507	38,650	45,507
Warrant liability	7,673	6,550	7,673
Asset retirement obligations	1,081	959	1,081
Total noncurrent liabilities	54,261	46,159	54,261
Redeemable Preferred A-3 interests and accrued dividends	5,896	5,458	—
Redeemable Preferred A-2 interests and accrued dividends	36,205	34,163	—
Members' equity (deficit):			
Preferred A interests, no par value. Authorized 100,000,000 units; 16,886,750 units issued and outstanding at December 31, 2017 and 2016	16,887	16,887	—
Preferred A-1 interests, no par value. Authorized 100,000,000 units; 21,526,850 units issued and outstanding at December 31, 2017 and 2016	21,883	21,883	—
Common interests, no par value. Authorized 500,000,000 units; 121,228,353 and 118,785,104 units issued and outstanding at December 31, 2017 and 2016, respectively	12,727	11,243	—
Unaudited pro forma common stock, $0.001 par value. Authorized 1,000,000,000 shares; 250,000,000 issued and outstanding at December 31, 2017	—	—	247
Additional paid-in capital	—	1,460	90,871
Accumulated deficit	(120,093)	(108,670)	(117,613)
Total members' deficit	(68,596)	(57,197)	(26,495)
Total liabilities and members' equity	$ 43,116	$ 39,389	$ 43,116

See accompanying notes to the consolidated financial statements

MonoSol Rx, LLC
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per membership interest and per share data amounts)

	Year Ended December 31, 2017	Year Ended December 31, 2016
Revenues	$ 66,918	$ 51,785
Costs and expenses:		
Manufacture and supply	19,820	16,378
Research and development	22,133	15,450
Selling, general and administrative	25,078	20,804
Total costs and expenses	67,031	52,632
Operating loss	(113)	(847)
Other expenses:		
Interest expense	(7,707)	(6,143)
Loss on extinguishment of debt	—	(757)
Loss on impairment of investment	—	(1,006)
Change in fair value of warrant	(1,123)	(750)
Other income (expense)	—	(99)
Net loss before income taxes	(8,943)	(9,602)
Income taxes	—	—
Net loss	(8,943)	(9,602)
Dividends on redeemable preferred interests	(2,480)	(2,342)
Net loss attributable to members' interests	(11,423)	(11,944)
Comprehensive loss	$ (11,423)	$ (11,944)
Net loss per membership interest basic and diluted	$ (0.09)	$ (0.10)
Weighted-average number of membership interests outstanding basic and diluted	121,228,353	118,785,104
Unaudited pro forma net loss (Note 2(D))	$ (8,943)	
Unaudited pro forma net loss per share of common stock (Note 2(D))	$ (0.04)	
Unaudited pro forma basic and diluted weighted-average shares of common stock outstanding (Note 2(D))	246,768,153	

See accompanying notes to the consolidated financial statements

MonoSol Rx, LLC
Consolidated Statements of Changes in Members' Deficit
(In thousands, except unit amounts)

	Preferred A interests		Preferred A-1 interests		Common interests		Additional paid-in capital	Accumulated deficit	Total members' deficit
	Units	Amount	Units	Amount	Units	Amount			
Balance at December 31, 2015	16,886,750	$16,887	21,526,850	$21,883	118,785,104	$11,243	$ 1,460	$ (96,726)	$ (45,253)
Dividends on preferred interests	—	—	—	—	—	—	—	(2,342)	(2,342)
Net loss	—	—	—	—	—	—	—	(9,602)	(9,602)
Balance at December 31, 2016	16,886,750	16,887	21,526,850	21,883	118,785,104	11,243	1,460	(108,670)	(57,197)
Dividends on preferred interests	—	—	—	—	—	—	—	(2,480)	(2,480)
Net loss	—	—	—	—	—	—	—	(8,943)	(8,943)
Issuance of common interests upon exercise of warrants	—	—	—	—	2,443,249	1,484	(1,460)	—	24
Balance at December 31, 2017	16,886,750	$16,887	21,526,850	$21,883	121,228,353	$12,727	$ —	$ (120,093)	$ (68,596)

See accompanying notes to the consolidated financial statements

MonoSol Rx, LLC
Consolidated Statements of Cash Flows
(In thousands)

	For the Year Ended December 31,	
	2017	2016
Cash flows from operating activities:		
Net loss	$ (8,943)	$ (9,602)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:		
Depreciation and amortization	3,750	3,840
Loss on impairment of investment	—	1,006
Change in fair value of warrant	1,123	750
Asset retirement obligation accretion	122	107
Amortization of intangible	51	51
Amortization of debt issuance costs and discounts	1,860	857
Loss on extinguishment of debt	—	757
Equity in milestone revenue of affiliate	—	254
Loss on sale of investment	—	95
Non-cash interest expense	33	(13)
Bad debt (recovery) provision	(53)	16
Changes in operating assets and liabilities:		
Trade receivables and other receivables	4,691	(6,508)
Inventories	(1,128)	(1,587)
Prepaid expenses	(171)	(82)
Accounts payable	2,943	1,650
Accrued expenses	1,001	452
Deferred revenue	545	(218)
Net cash provided by (used for) operating activities	5,824	(8,175)
Cash flows from investing activities:		
Capital expenditures	(2,068)	(976)
Proceeds from sale of investment	—	1,166
Net cash (used for) provided by investing activities	(2,068)	190
Cash flows from financing activities:		
Proceeds from warrant exercise	24	—
Proceeds from issuance of debt	5,000	45,000
Debt repayment	—	(37,500)
Payments for debt issuance costs	(610)	(1,248)
Payment of premium on early extinguishment of debt	—	(563)
Net cash provided by financing activities	4,414	5,689
Net increase (decrease) in cash and cash equivalents	8,170	(2,296)
Cash and cash equivalents:		
Beginning of period	9,209	11,505
End of period	$ 17,379	$ 9,209
Supplemental disclosures of cash flow information:		
Cash payments for interest	$ 5,814	$ 5,047
Capital expenditures included in accounts payable	20	192
Accrued Series A-2 and A-3 preferred dividends	2,480	2,342

See accompanying notes to the consolidated financial statements

MonoSol Rx, LLC

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(In thousands, except unit and per unit information)

1. Nature of Business

MonoSol Rx, LLC ("MonoSol" or "the Company") is a specialty pharmaceutical company focused on identifying, developing and commercializing differentiated products to address unmet medical needs. The Company has a late-stage proprietary product pipeline focused on the treatment of diseases of the central nervous system, or CNS. The Company's major customer has global operations headquartered in the United Kingdom with principal operations in the United States; other customers are principally located in the United States.

The Company conducts its production activities at facilities located in Portage, Indiana, and maintains its headquarters and its primary research laboratory in Warren, New Jersey.

The Company has incurred operating losses since inception and had an accumulated deficit of $120,093 and $108,670 as of December 31, 2017 and 2016, respectively. The Company expects to continue to incur net losses for at least the next several years and is highly dependent on its ability to find additional sources of funding in the form of debt or equity financings to fund its operations. Management believes that its cash and cash equivalents of $17,379 at December 31, 2017 combined with expected revenue from partnered product activities are sufficient to fund operations through at least May 2019. Management expects that future sources of funding may include new or expanded partnering arrangements and sales of equity or debt securities. Adequate additional funding may not be available to the Company on acceptable terms or at all. The failure to raise capital as and when needed could have a negative impact on the Company's financial condition and ability to pursue business strategies. The Company may be required to delay, reduce the scope of or eliminate research and development programs, or obtain funds through arrangements with collaborators or others that may require the Company to relinquish rights to certain product candidates that the Company might otherwise seek to develop or commercialize independently.

The Company changed its name to Aquestive Therapeutics, Inc. on January 1, 2018, and at the same time became a Delaware corporation.

2. Significant Accounting Policies

(A) Basis of Presentation

These consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. This basis of accounting contemplates the recovery of the Company's assets and the satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

(B) Principles of Consolidation

These consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, MonoSol Rx, Inc. Other than corporate formation activities, MonoSol Rx, Inc. has conducted no commercial, developmental or operational activities and has no customers or vendors.

(C) Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates.

(In thousands, except unit and per unit information)

(D) Unaudited Pro Forma Presentation

The unaudited pro forma balance sheet information as of December 31, 2017 reflects the issuance of 246,768,153 shares of common stock in exchange for all outstanding shares of preferred A interests, preferred A-1 interests, common interests, redeemable preferred A-2 interests and accrued dividends and redeemable preferred A-3 interests and accrued dividends as of December 31, 2017 prior to the closing of an initial public offering.

Unaudited pro forma net loss per share attributable to common stockholders for the year ended December 31, 2017 is computed using the weighted-average number of shares of common stock outstanding after giving effect to the conversion of all Common and Preferred Interests into shares of the common stock as if such conversion had occurred at the beginning of the period presented, or the date of original issuance, if later. Accordingly, the pro forma basic and diluted net loss per share attributable to common stockholders does not include the effects of the cumulative preferred stock dividends.

(E) Net Loss Attributable to Members' Interest

Basic net loss per membership interest is calculated by dividing net loss attributable to members' interest less cumulative preferred stock dividends. During periods of income, the Company allocates participating securities a proportional share of income determined by dividing total weighted-average participating securities by the sum of the total weighted-average common interests and participating securities (the "two class method"). The Company's convertible preferred stock participates in any dividends declared by the Company and are therefore considered to be participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, the Company allocates no loss to participating securities because they have no contractual obligation to share in the losses of the Company. Diluted net loss per membership interest is calculated by adjusting weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method and if-converted methods. For purposes of the diluted net loss per membership interest calculation, convertible preferred stock and stock options are considered to be common stock equivalents, but have been excluded from the calculation of diluted net loss per membership interest, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for all periods presented.

	For the Year Ended December 31,	
	2017	2016
Numerator:		
Net income (loss)	$ (8,943)	$ (9,602)
Accrued dividends on redeemable preferred interests	(2,480)	(2,342)
Loss attributable to common shares - basic and diluted	(11,423)	(11,944)
Denominator:		
Weighted-average number of common shares - basic and diluted	121,228,353	118,785,104
Loss per common share - basic and diluted	$ (0.09)	$ (0.10)

(In thousands, except unit and per unit information)

The unaudited pro forma net loss per share of common stock outstanding is computed using the weighted-average number of shares of common stock outstanding after giving effect to the conversion of all issued and outstanding shares of redeemable preferred interests to common stock as if such conversion occurred at January 1, 2017, or at the date of original issuance, if later.

	For the Year Ended December 31,	
	2017	2016
Numerator:		
Net income (loss) attributable to common shares - basic and diluted	$ (11,423)	$ (11,944)
Add: Redeemable dividends on preferred interests	2,480	2,342
Net income (loss) attributable to common shares - basic and diluted	(8,943)	(9,602)
Denominator:		
Weighted-average number of common shares - basic and diluted	121,228,353	118,785,104
Add: Assumed conversion of redeemable preferred interests to common stock	125,539,800	125,539,800
Pro forma weighted-average shares outstanding	246,768,153	244,324,904
Pro forma net income (loss) per share - basic and diluted	$ (0.04)	$ (0.04)

(F) Deferred Transaction Costs

Deferred Transaction costs, primarily costs of direct incremental legal, accounting and other fees relating to the Company's contemplated initial public offering ("IPO"), are capitalized as incurred. The deferred transaction costs will be offset against IPO proceeds upon the consummation of the offering. In the event the IPO is terminated, which would include a postponement of 90 days or greater, any deferred transaction costs will be expensed. The Company has capitalized costs totaling approximately $1,050 that have been incurred in connection with ongoing equity raising initiatives. These amounts are recorded in Other assets.

(G) Off-Balance Sheet Risk and Concentration of Credit Risk

Cash and cash equivalents are maintained at one federally insured financial institution. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to any credit risk due to the financial position of the banking institution. The Company has no off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

(H) Segment Information

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company manages its operations as a single segment for purposes of assessing performance and making operating decisions.

(I) Fair Value of Financial Instruments

FASB guidance specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

- Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.
- Level 2 – Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly (*e.g.,* quoted prices of similar assets or liabilities in active markets, or quoted prices for identical or similar assets or liabilities in markets that are not active). Level 2 includes financial instruments that are valued using models or other valuation methodologies. The Company had no Level 2 assets or liabilities as of December 31, 2017 and 2016.
- Level 3 – Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when the fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable. The Company's Level 3 liabilities consisted of warrants totaling $7,673 and $6,550 at December 31, 2017 and 2016, respectively. The Company's warrant liability is stated at fair value.

The carrying amounts reported in the balance sheets for trade and other receivables, prepaid and other current assets, accounts payable, accrued expenses and deferred revenue approximate fair value based on the short-term maturity of these instruments.

(J) Cash and Cash Equivalents

The Company considers investments with an original maturity of three months or less to be cash equivalents. At December 31, 2017 and 2016, the Company had no cash equivalents.

(K) Foreign Currency

The functional currency of the Company's wholly-owned subsidiary is the U.S. dollar.

(L) Trade Receivables

The Company's credit terms generally range from 30 to 60 days, depending on the customer and type of invoice. Trade receivables are carried at original invoice amount less an estimate of doubtful receivables based on a review of all outstanding amounts on a periodic basis. Management determines the allowance for doubtful accounts by identifying troubled accounts and, in the absence of historical experience, applies an estimate that is believed to be a reasonable indicator of future potential losses. Trade receivables are written off when deemed uncollectible. Recoveries of trade receivables previously written off are recorded when received.

(M) Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined on a first-in, first-out basis. Inventory includes the cost of materials, production labor and overhead. The Company regularly reviews its inventories for impairment and reserves are established when necessary.

(N) Property and Equipment

Property and equipment are stated at cost. Leasehold improvements are amortized over the shorter of the term of the lease or their estimated useful lives. Depreciation of equipment, furniture and fixtures is calculated using the straight-line method over the estimated useful lives of the assets. Repairs and

maintenance costs are expensed. The Company reviews the recoverability of all long-lived assets, including the related useful life, whenever events or changes in circumstances indicate that the carrying value amount of a long-lived asset may not be recoverable.

(O) Impairment of Long-Lived Assets

In accordance with the Subsections of FASB ASC Subtopic 360-10, *Property, Plant and Equipment – Overall*, long-lived assets, such as property and equipment and intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. That carrying value is considered unrecoverable if it exceeds the sum of the undiscounted cash flows expected from the use and eventual disposition of the asset.

As a result of management's evaluation of the recoverability of the carrying value of long-lived assets subject to ASC 360-10, no impairment charges were recorded for the years ended December 31, 2017 and 2016.

(P) Investments

For entities or ventures that are under shared control, owned and managed equally by the Company and a third party and in which the Company is a direct and active participant in the entity's operating activities and through which it is directly exposed to the risks and rewards of operating activities, the Company's investments are carried at cost. Acting as principal in carrying out its operational responsibilities, the Company records its share of related revenue and its expense transactions reflecting all of that revenue and its third-party expenses in its consolidated financial statements in accordance with the nature of the revenue or in a manner to proportional consolidation.

(Q) Intangible Assets

Intangible assets include the costs of acquired composition and process technologies and the costs of purchased patents used in the manufacture of orally soluble film. The Company amortizes these assets using the straight-line method over the shorter of their legal lives or estimated useful lives.

(R) Patent Costs

Patent procurement, prosecution and defense litigation costs are expensed as incurred, including costs for patent continuation applications. The Company's primary domestic and international patents expire between 2022 and 2031.

(S) Retirement Plan

The Company maintains a 401(k)-retirement plan for its employees that is intended to qualify under Sections 401(a) and 501(a) of the U.S. Internal Revenue Code of 1986, as amended ("Code"), in 2016. The Company provides all active employees with 100% matching contribution equal to 6% of an employee's eligible compensation. These safe harbor employer match contributions vest as follows: less than one year: 0%; one year: 20%; two years: 40%; three years: 60%; four years: 80%; and five years: 100%.

(T) Research and Development

Costs incurred in connection with research and development activities are expensed as incurred. Research and development expenses include (i) employee-related expenses, including salaries, benefits, travel and share-based compensation expense, (ii) external research and development expenses incurred under arrangements with third parties, such as contract research and contract manufacturing organizations, investigational sites and consultants, (iii) the cost of acquiring, developing and manufacturing clinical study materials, and (iv) costs associated with preclinical and clinical activities and

regulatory operations. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity is performed or when the goods have been received, rather than when payment is made, in accordance with ASC 730, *Research and Development.*

(U) Income Taxes

From its founding through October 31, 2017, the Company was a limited liability company ("LLC") treated as a partnership for income tax purposes. From November 1, 2017 through December 31, 2017, the LLC elected to be taxed as a C corporation.

From November 1, 2017, the Company accounts for income taxes under the asset and liability method, which requires deferred tax assets and liabilities to be recognized for the estimated future tax consequences attributable to differences between financial statement carrying amounts and respective tax bases of existing assets and liabilities, as well as net operating loss carryforwards and research and development credit. Valuation allowances are provided if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

(V) Revenue Recognition

Pursuant to FASB ASC Topic 605, *Revenue Recognition*, revenue is recognized when there is persuasive evidence of an agreement, title has passed or delivery has occurred, the price is fixed and determinable, and collection is reasonably assured.

Manufacture and Supply Revenue – The Company records revenues when products are shipped and title passes to the customers.

Co-development and Research Fees – Co-development and research fees are earned through performance of specific tasks, activities or completion of stages of development defined within a contractual arrangement with a customer. The nature of these performance obligations, broadly referred to as milestones or deliverables, are usually dependent on the scope and structure of the project as contracted, as well as the complexity of the product and the specific regulatory approval path necessary for that product. Accordingly, the duration of the Company's research and development projects may range from several months to approximately three years. Although each contractual arrangement is unique, common milestones included in these arrangements include those for the performance of efficacy and other tests, reports of findings, formulation of initial prototypes, production of stability clinical and/or scale-up batches, and stability testing of those batches. Additional milestones may be established and linked to clinical results of the product submission and/or approval of the product by the FDA and the commercial launch of the product. Co-development and research fees are recognized when related milestones are completed and delivered and, in some cases, accepted by the customer.

License and Royalty Revenue – License revenue is recognized in accordance with the terms of the license agreement. The revenue will be recognized ratably over the initial term of the license agreement. If the term of the license is perpetual, the Company will recognize the revenue upon the execution of the license as long as there are no contingencies in the license agreement. If a contingency exists, the revenue will need to be deferred until such time that the contingencies are lifted. Royalty revenue is recognized in accordance with contractual rates when they can be reasonably estimated based on reported sales data and when collection is reasonably assured. In the event that reasonable sales data is unavailable, revenue is recognized when royalty reports are received.

Collaborative Arrangements – A contractual arrangement falls within the scope of FASB ASC Subtopic 808-10, Collaborative Arrangements, if the arrangement requires the parties to be active participants and the arrangement exposes the parties to significant risks that are tied to the commercial success of the endeavor. Costs incurred and revenues generated on sales to third parties are reported in

the consolidated statement of operations based on the guidance in FASB ASC Subtopic 605-45, *Revenue Recognition – Principal Agent Considerations*. Revenue earned from collaboration partners as of December 31, 2017 and 2016 was not material.

(W) Share-Based Payments

The Company issues share-based payments under the terms of its Performance Unit Plans (the "PUP Plans"). The cost of employee services received in exchange for equity-based awards are determined based on FASB ASC Topic 718, *Compensation – Stock Compensation* using the grant-date fair value of the awards. Under the Company's PUP Plans, all outstanding equity-based payments are to be recognized as an expense based on their fair value at the measurement date, which is delayed until achievement of specified performance conditions can be considered probable. At the time that all contingencies are satisfied, the performance units granted to both employees and consultants will be reflected as liability-classified instruments based on the application of FASB ASC Topic 718.

(X) Asset Retirement Obligations

FASB ASC Subtopic 410-20, *Asset Retirement and Environmental Obligations – Asset Retirement Obligations*, addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. The Company's asset retirement obligation ("ARO") consists of estimated future spending to remove certain leasehold improvements and return each leased facility to its original condition. The Company records an ARO asset (a component of property and equipment) and associated liability equal to the present value of the estimated future spending at the date the asset is placed in service. Spending estimates are discounted at the credit-adjusted risk-free rate. The ARO asset is amortized on the straight-line method over the lesser of its expected life or the lease term and the ARO liability is accreted over the lesser of expected life or the lease term.

(Y) Comprehensive Loss

Comprehensive loss is the change in members' equity (deficit) from transactions and other events and circumstances other than those resulting from investments by members and distributions to members.

(Z) Recent Accounting Pronouncements

As a public emerging growth company, the Company has elected to take advantage of the extended transition period afforded by Jumpstart Our Business Startups Act for the implementation of new or revised accounting standards and, as a result, the Company will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public emerging growth companies.

From time to time, new accounting pronouncements are issued by the FASB and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The standard will apply one comprehensive revenue recognition model across all contracts, entities, and sectors. The core principle of the new standard is that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Once effective, ASU 2014-09 will replace most of the existing revenue recognition requirements in U.S. GAAP. The FASB also issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which

deferred the effective date of the standard one year. As a result, the new standard is effective for annual reporting periods beginning after December 15, 2019, including interim periods within the reporting period. The Company is currently assessing the effect that adoption of the new standard will have on its consolidated financial statements. As of part of the Company's assessment, an entity can elect to apply the guidance under one of the following two methods: (i) retrospectively to each prior reporting period presented, referred to as the full retrospective method, or (ii) retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings, referred to as the modified retrospective method. The Company is in the process of its initial assessment of the potential changes from adopting ASU No. 2014-09. The initial assessment consists of a review of a representative sample of contracts, discussions with key stakeholders, and a cataloging of potential impacts on its consolidated financial statements, accounting policies, financial control, and operations. The Company has not yet completed its final review of the impact; however, the Company anticipates applying the modified retrospective method when implementing this guidance. As a result, this standard is effective for the Company for annual reporting periods beginning after December 15, 2019. The Company continues to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact its initial conclusions.

In January 2016, the FASB issued revised guidance governing accounting and reporting of financial instruments. This guidance requires that equity investments with readily determinable fair values that are classified as available-for-sale be measured at fair value with changes in value reflected in current earnings. This guidance also simplifies the impairment testing of equity investments without readily determinable fair values and alters certain disclosure requirements. ASU No. 2016-01, *Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*, also provides guidance as to classification of the change in fair value of financial liabilities. These revised standards are effective for the Company for annual periods in fiscal years beginning after December 15, 2018. The Company is currently evaluating the impact of these revised standards.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* which establishes a comprehensive new lease accounting model. The new standard: (i) clarifies the definition of a lease; (ii) requires a dual approach to lease classification similar to current lease classifications; and (iii) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use asset for leases with a lease-term of more than twelve months. The new standard is effective for the Company for fiscal years and interim periods beginning after December 15, 2019 and requires modified retrospective application. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. This guidance simplifies aspects of accounting for employee share-based payments, including income tax consequences, classification of awards as either equity or liabilities, and classifications within the statement of cash flows. This guidance is effective for annual periods beginning after December 15, 2017, with early adoption permitted. Under the Company's PUP Plans (note 18), vested grants may not be exercised prior to either a change in control of the Company or completion of an IPO, rendering the grants contingent and requiring deferred expense recognition until either of the conditions is satisfied. Accordingly, the adoption of ASU 2016-09 will have no impact on the Company's consolidated financial statements until these contingencies are met.

In June 2016, the FASB issued, ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326)*, amending existing guidance on the accounting for credit losses on financial instruments within its scope. The guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt

(In thousands, except unit and per unit information)

securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The new guidance is effective for the Company beginning after December 15, 2020. The Company is currently evaluating the impact of adoption on its consolidated financial statements

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, providing* guidance on the classification of certain cash receipts and payments in the statement of cash flows intended to reduce diversity in practice. The guidance is effective for the Company for fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company is currently evaluating the effect of the standard on its Consolidated Statement of Cash Flows.

3. Revenues and Trade Receivables, Net

The Company's revenue was comprised of the following:

	For the Year Ended December 31,	
	2017	2016
Manufacture and supply revenue	$ 40,092	$ 37,324
License and royalty revenue	23,133	11,320
Co-development and research fees	3,693	3,141
Revenues	$ 66,918	$ 51,785

Trade receivables, net consist of the following:

	December 31,	
	2017	2016
Trade receivables	$ 6,156	$ 10,764
Less: allowance for bad debts	(55)	(108)
Trade receivables, net	$ 6,101	$ 10,656

Other nontrade receivables totaled $78 and $161 as of December 31, 2017 and 2016, respectively, consisting primarily of reimbursable costs incurred on behalf of a major customer.

The following table presents the changes in the allowance for bad debts account for the years ended December 31,

	2017	2016
Allowance for doubtful accounts at beginning of year	$ 108	$ 92
Additions charged to bad debt expense	0	16
Recoveries of amounts previously reserved	(53)	0
Allowance for doubtful accounts at end of year	$ 55	$ 108

4. Customer Concentrations

Customers are considered major customers when sales exceed 10% of total net sales for the period or outstanding receivable balances exceed 10% of total receivables. During 2017, one customer represented 88% of the total revenue for the period. During 2016, the Company had two customers meeting this criteria with approximately 76% and 17% of the total revenue for the period.

As of December 31, 2017 and 2016, the Company's outstanding receivable balance from the Company's major customer represented approximately 93% and 97%, respectively, of total receivables. As of December 31, 2016, our second largest customer had no oustanding receivable balance.

5. Material Agreements

Commercial Exploitation Agreement with Indivior

In August 2008, the Company entered into a Commercial Exploitation Agreement with Reckitt Benckiser Pharmaceuticals, Inc. (the "Indivior License Agreement"). Reckitt Benckiser Pharmaceuticals, Inc. was later succeeded to in interest by Indivior, Inc. ("Indivior"). Pursuant to the Indivior License Agreement, the Company agreed to manufacture and supply Indivior's requirements of Suboxone, a sublingual film formulation, both inside and outside the United States on an exclusive basis.

Under the terms of the Indivior License Agreement, the Company is required to manufacture Suboxone in accordance with current Good Manufacturing Practice standards and according to the specifications and processes set forth in the related quality agreements the Company entered into with Indivior. Additionally, the Company is required to obtain Active Pharmaceutical Ingredients ("API") for the manufacture of Suboxone directly from Indivior. The Indivior License Agreement specifies a minimum annual threshold quantity of Suboxone that the Company is obligated to fill and requires Indivior to provide the Company with a forecast of its requirements at various specified times throughout the year.

In addition to the purchase price for the Suboxone supplied, Indivior is required to make certain single digit percentage royalty payments tied to net sales value (as provided for in the Indivior License Agreement) in each of the United States and in the rest of the world subject to annual maximum amounts. In the event that Indivior has paid the Company a specified aggregate royalty amount in royalties on Suboxone sold in the United States, then it will be required to prepay to the Company, an additional agreed payment amount, after which all obligations of Indivior to pay royalties on Suboxone sold in the United States will terminate. Except as set forth in the prior sentence, Indivior's royalty obligations to the Company continue in the United States and the rest of the world until the expiration of all of the patents (either in the United States or other territories) or upon written notice by Indivior subject to Indivior being required to pay the Company a final royalty payout. Indivior exercised its right to buy out its future royalty obligations in the United States in 2012. Indivior remains obligated to pay royalties for all sales outside the United States.

The Indivior License Agreement contains customary contractual termination provisions for breach or in the event of bankruptcy or corporate dissolution, the intellectual property surrounding Suboxone is found to be invalid, or either party commits a material breach of the Indivior License Agreement. Additionally, Indivior may terminate if the U.S. Food and Drug Administration ("FDA") or other applicable regulatory authority declares the Company's manufacturing site to no longer be suitable for the manufacture of Suboxone or Suboxone is no longer suitable to be manufactured due to health or safety reasons. The initial term of the Indivior License Agreement was seven years from the commencement date. Thereafter, the Indivior License Agreement automatically renews for successive one year periods, unless Indivior provides the Company with written notice of its intent not to renew at least one year prior to the expiration of the initial or renewal term.

Supplemental Agreement with Indivior

On September 24, 2017, the Company entered into an agreement with Indivior (the "Indivior Supplemental Agreement") to clarify the scope of the relationship between the parties. Under the Indivior Supplemental Agreement, the Company is entitled to receive certain payments from Indivior commencing on the date of the agreement through January 1, 2023. In consideration for the rights granted to Indivior under the Indivior Supplemental Agreement, the Company received a non-refundable payment of $17,000, which was recognized as revenue in 2017 and is presented in License and royalty revenue above. The Company has also received $9,250 in February 2018 as a part of this agreement. In addition

to amounts received, the Company may receive up to an additional $49,000, consisting of a royalty equal to a low single digit percentage of net revenue earned by Indivior on Suboxone sales and performance-based milestone payments, with the aggregate payment amounts under the Indivior Supplemental Agreement capped at $75,000.

All payments made by Indivior to the Company pursuant to the Indivior Supplemental Agreement are in addition to, and not in place of, any amounts owed by Indivior to the Company pursuant to the Indivior License Agreement. Indivior's payment obligations under the Indivior Supplemental Agreement are subject to certain factors affecting the market for Suboxone and may terminate prior to January 1, 2023 in the event certain contingencies relating to such market occur.

License Agreement with Sunovion Pharmaceuticals, Inc.

In April 2016, the Company entered into a license agreement with Cynapsus Therapeutics Inc. (which was later succeeded to in interest by Sunovion Pharmaceuticals, Inc. ("Sunovion")) (the "Sunovion License Agreement"), pursuant to which the Company granted Sunovion an exclusive, worldwide license (with the right to sub-license) to certain intellectual property, including existing and future patents and patent applications, covering all oral films containing APL-130277 (apomorphine) for the treatment of off episodes in Parkinson's disease patients, as well as two other fields.

Under the Sunovion License Agreement, the Company received milestone payments of $14,000, of which $5,000 and $9,000 for years ended December 31, 2017 and 2016, respectively, are presented in License and royalty revenue above. The Company is eligible to receive remaining milestone payments of up to $11,000 for certain regulatory events and up to $20,000 for commercial milestone events that are contingent on the achievement of certain sales levels. In addition to the milestone payments, the Company is entitled to receive low single digit percentage royalty payments on global net sales of products commercialized by Sunovion that include apormorphine as their API.

Absent early termination, the Sunovion License Agreement continues (on a country-by-country basis) until the expiration of all applicable licensed patents. Upon termination, all rights to intellectual property granted to Sunovion to develop and commercialize products will revert to the Company and Sunovion must continue to pay royalties to the Company on each sale of their remaining inventory of products commercialized by Sunovion which include apormorphine as their API.

Collaboration and License Agreement with Mitsubishi Tanabe

In August 2017, the Company entered into an agreement with Mitsubishi Tanabe ("MT") to perform feasability studies related to Radicava, MT's Amyotrophic Lateral Sclerosis treatment using the compound edaravone. The activities for this arrangement were not material in 2017.

Agreement to Terminate CLA with KemPharm

In March 2012, the Company entered into an agreement with KemPharm, Inc. ("KemPharm"), to terminate a Collaboration and License Agreement entered into in April 2011, under this arrangement, we have the right to receive payments, including, but not limited to, royalty payments on any license of KP415, the sale of KP415 to a third party, the commercialization of KP415 and the portion of any consideration that is attributable to the value of KP415 and paid to KemPharm or its stockholders in a change of control transaction. The Company has not received payments under this arrangement in 2017 and 2016.

(In thousands, except unit and per unit information)

6. Inventory

Inventory consists of the following:

	December 31, 2017	December 31, 2016
Raw material	$ 725	$ 611
Packaging material	2,225	1,433
Finished goods	1,064	842
Total inventory	$ 4,014	$ 2,886

7. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist primarily of costs incurred in advance of services being received, including insurance, software licenses and service agreements.

	December 31, 2017	December 31, 2016
Insurance	$ 148	$ 125
Software licenses	125	54
Service agreements	75	29
Medical premiums	70	60
Subscriptions	44	8
Lab equipment	39	58
Memberships	30	27
Other	60	59
Total prepaid expenses and other current assets	$ 591	$ 420

8. Property and Equipment, Net

	Useful Lives	December 31, 2017	December 31, 2016
Machinery	3-15 yrs	$ 20,056	$ 19,130
Furniture and fixtures	3-15 yrs	1,109	1,066
Leasehold improvements	(a)	21,271	21,110
Computer, network equipment and software	3-7 yrs	2,108	1,387
Construction in progress		921	684
		45,465	43,377
Less: accumulated depreciation and amortization		(32,005)	(28,255)
Total property and equipment, net		$ 13,460	$ 15,122

(a) Leasehold improvements are amortized over the shorter of the lease term or their estimated useful lives.

Total depreciation and amortization related to property and equipment were $3,750 and $3,840 for the years ended December 31, 2017 and 2016, respectively.

(In thousands, except unit and per unit information)

9. Intangible Assets

The following table provides the components of identifiable intangible assets, all of which are finite lived:

	December 31, 2017	December 31, 2016
Purchase technology-based intangible	$ 2,358	$ 2,358
Purchased patent	509	509
	2,867	2,867
Less: accumulated amortization	(2,613)	(2,562)
Intangible assets, net	$ 254	$ 305

Amortization expense was $51 for each of the years ended December 31, 2017 and 2016. During the remaining life of the purchased patent, estimated annual amortization expense is $51 for each of the years from 2018 to 2022.

10. Investments

During the fourth quarter of 2016, the Company sold all holdings of equity interests in Midatech Pharma, PLC, realizing proceeds of $1,166. Through a series of investments in Midatech shares, warrants and convertible loan notes, the Company's investment grew to a total of $5,802 between 2008 and 2013. As a result of a series of dilutive equity transactions executed by Midatech between 2013 and 2015, the Company's ownership position declined from 12.4% to 2.6% as of December 31, 2015, and the Company then determined to monetize this asset. As a result of this dilution, declining market valuations and the decision to liquidate this investment, impairment charges aggregating to $1,006 were reflected in earnings in 2016. The Company's investment in this joint venture, carried at cost, totaled $6 as of December 31, 2017 and is recorded in Other assets on the consolidated balance sheets.

Concurrent with the sales of these interests in 2016, losses on disposals totaling $95 were recognized.

In addition to its investments in Midatech shares, pursuant to the agreement between the parties, the Company also funded certain project development costs. These costs are expensed to research and development as paid and totaled $4,842 through December 31, 2017.

In 2011, Midatech Ltd. and the Company entered into a Joint Venture Agreement for the development and commercialization of diabetes-related products and formed MidaSol Therapeutics (the "JV") to conduct planned activities. The agreement provides each of the two venture partners with 50% ownership interests, identical voting and management rights and responsibilities, equal representation on the governing four-member board of managers, the requirement to contribute relevant intellectual property by each party and equal sharing of profits and losses to each party for JV products or services. Each of the parties actively participates in the conduct and performance of the venture's undertakings, each acts as principal in the completion of its obligations and each is subject to the risks and rewards inherent in related joint operations. All of MidaSol's research, development, production and sales activities have been conducted through the facilities of each party and carried out by the parties' employees or contractors. For all products and services provided to its customers, except those related to research studies, costs are reimbursed to the parties from earned revenues prior to the sharing of profits.

(In thousands, except unit and per unit information)

11. Accrued Expenses

Accrued expenses consisted of the following:

	December 31, 2017	December 31, 2016
Bonus	$ 3,257	$ 2,360
Payroll and benefits	548	585
Other	597	421
Total accrued expenses	$ 4,402	$ 3,366

12. Loans Payable

On August 16, 2016, the Company entered into a Loan Agreement and Guaranty with Perceptive Credit Opportunities Fund, LP ("Perceptive"). At closing, the Company borrowed $45,000 from Perceptive and was permitted to borrow up to an additional $5,000 within one year of the closing date based upon achievement of a defined milestone. In March 2017, the Company met its performance obligations under the terms of the credit agreement with Perceptive and submitted a formal request to draw down the remaining $5,000 of its $50,000 credit facility. The loan proceeds have been used to pay the existing debt obligation of $37,500 due to White Oak Global Advisors, LLC, with the balance available for general business purposes. This debt retirement resulted in a loss on extinguishment of debt in the amount of $757, consisting primarily of early retirement fees, the write-off of unamortized debt discounts and acquisition fees and related legal expenses.

The loan from Perceptive will mature on August 16, 2020 and bears interest, payable monthly, at one-month LIBOR or 2% plus 9.75%, subject to a minimum rate of 11.75%. Commencing on January 31, 2019, seven monthly loan principal payments are due in the amount of $550. Thereafter, monthly principal payments in the amount of $750 are due through the maturity date, at which time the full amount of the remaining outstanding loan balance is due. The Company's tangible and intangible assets are subject to first priority liens to the extent of the outstanding debt. Other significant terms include financial covenants, change of control triggers and limitations on additional indebtedness, asset sales, acquisitions and dividend payments. As of December 31, 2017, the Company was in compliance with all financial covenants. As of December 31, 2017, the Company's carrying value of this loan payable approximates its fair market value. At closing, Perceptive received a warrant to purchase senior common equity interests representing 4.5% of the fully diluted common units of the Company on an as converted basis (see Note 13).

The Company capitalizes legal and other third-party costs incurred in connection with obtaining debt as deferred debt issuance costs, and applies the unamortized portion as a reduction of the outstanding face amount of the related loan in accordance with ASU 2015-03, *Interest – Imputation of Interest: Simplifying the Presentation of Debt Issuance Costs*. Similarly, the Company amortizes debt discounts, such as those represented by warrants issued to its lenders, and offsets those as a direct reduction of its outstanding debt. Amortization expense arising from deferred debt issuance costs and debt discounts for the years ended December 31, 2017 and 2016 were $1,860 and $857, respectively.

Unamortized deferred debt issuance costs and deferred debt discounts totaled $4,493 as of December 31, 2017 and $6,350 as of December 31, 2016.

13. Warrant Liability

The warrant issued to Perceptive in connection with the August 16, 2016 Loan Agreement expires on August 16, 2023 and has certain rights and preferences including anti-dilution adjustments so that, upon exercise, they will represent 4.5% of the Company's fully diluted common stock on an as converted basis.

The warrant also provides Perceptive with a put right which, if exercised under certain circumstances, would require the Company to purchase the warrant for $3,000 within the first year of the loan or $5,000 thereafter. These re-purchase terms may require net-cash settlement, and as a result, the appraised value of this warrant at the time of issuance of $5,800 is classified as a liability, rather than as a component of equity, and is treated as a debt discount, with the unamortized portion applied to reduce the face amount of the loan in the accompanying Consolidated Balance Sheet. The $1,123 change in value of this warrant liability from December 31, 2016 to December 31, 2017 and the $750 change in value of this warrant liability from the date of issuance to December 31, 2016 are reported in the accompanying Consolidated Statement of Operations as a “Change in fair value of warrant”.

The Company uses a third−party valuation to assist in determining the fair value of these warrants due to the absence of available Level 1 and Level 2 inputs. The appraisals at both the date of the issuance and the balance sheet date were based on unobservable Level 3 inputs. The first step in determining the fair value of the warrant liability is to determine the value of the aggregate equity of the Company which was estimated utilizing the income and market valuation approaches. A probability weighted return model was then utilized to allocate the aggregate equity value of the Company to the underlying securities. Estimates and assumptions impacting the fair value measurement include the following factors: the progress of the Company’s pipeline products since the prior valuations, including status of clinical trials; the Company’s progress towards an IPO, including selecting lead investment bankers to underwrite the planned IPO; discount rates of 26.5% and 34.5% for 2017 and 2016, respectively, and volatility rates of 90% and 80% for December 31, 2017 and 2016, respectively.

14. Commitments and Contingencies

(A). Leases

The Company has entered into various lease agreements for production and research facilities and offices. Most leases contain renewal options. Certain leases contain purchase options and require the Company to pay for taxes, maintenance and operating expenses. All of the Company’s leases are classified as operating leases.

Production and Research Facilities, Portage, Indiana

The Company leases a 73,000-square-foot facility (Ameriplex) in Portage, Indiana, to house additional packaging, R&D and other operations. As amended, this lease has a term that extends through September 30, 2022 and contains a renewal option that could extend the lease through September 30, 2026.

The Company also leases its current 8,400-square-foot production facility (Melton) in Portage, Indiana, which houses certain research and development offices and current good manufacturing practices, or cGMP, manufacturing operations. The lease contains an option to purchase the facility at any time during the lease term along with a right of first refusal to purchase the facility. In October 2012, the Company entered into an additional five-year extension of the lease of this facility, through March 31, 2018, under the same terms and conditions. In October 2017, the Company extended its lease located in Portage, Indiana, which will expire during March 2023 under the same terms and conditions as its former lease.

Office and Laboratory Facilities, Warren, New Jersey

The Company leases its headquarters and principal laboratory facility in Warren, New Jersey. Pursuant to various amendments in February 2011, June 2012 and May 2013, the Company has secured additional space to provide for the growth of its laboratory facilities and corporate and administrative requirements. The lease included five two-year renewal options, one of which was exercised in July 2016 to extend this lease through August 31, 2018. During February 2018, the Company extended this lease by eighteen months through February 28, 2020.

(In thousands, except unit and per unit information)

Rent Expense and Commitments

Rent expense for all leased manufacturing facilities and sales, laboratory and office space were $1,344 and $1,301 for the years ended December 31, 2017 and 2016, respectively.

The following schedule presents future minimum lease payments under operating leases as of December 31, 2017, including those derived from renewal options that are deemed noncancelable under FASB ASC Section 840-10-35, *Leases - Subsequent Measurement*:

	Amount
2018	$ 967
2019	801
2020	808
2021	815
2022	682
Thereafter	65
Total	$ 4,138

(B). Facility Construction Obligation

In December 2011, the Company entered into an agreement with a major customer to construct a packaging suite at its Ameriplex facility for a fee of $2,500, which the Company has amortized ratably over the five-year preferred-use period provided under that agreement, culminating in recognition of $769 during 2016.

(C). Litigation and Contingencies

The Company is involved in various claims, legal proceedings and investigations, including (as of December 2017, except where noted below) those described below. While it is not feasible to predict the outcome of such pending claims, proceedings and investigations with certainty, management is of the opinion that their ultimate resolution should not have a material adverse effect on the Company's financial position, cash flows, or results of operations, except where noted below.

Beginning in August 2013, the Company was informed of abbreviated new drug application ("ANDA") filings in the United States by Watson Laboratories, Inc. (now Actavis Laboratories, Inc. ("Actavis")), Par Pharmaceutical, Inc. ("Par"), Alvogen Pine Brook, Inc. ("Alvogen"), Teva Pharmaceuticals USA, Inc. ("Teva"), Sandoz Inc. ("Sandoz") and Mylan Technologies Inc. ("Mylan") for the approval by the FDA of generic versions of Suboxone Sublingual Film in the United States. The Company filed patent infringement lawsuits against all six generic companies in the U.S. District Court for the District of Delaware. By a court order dated August 22, 2016, the Company's ANDA patent litigation case against Sandoz has been dismissed without prejudice for lack of subject matter jurisdiction because Sandoz is no longer pursuing a Paragraph IV certification for its proposed generic version of Suboxone Sublingual Film, and therefore is no longer challenging the validity or noninfringement of our Orange Book-listed patents. The case against Mylan was settled and a Consent Judgment was entered in September 2017 disposing of the entire case as to Mylan. Dr. Reddy's Laboratories ("Dr. Reddy's) acquired from Teva the ANDA filings for Teva's buprenorphine HCl and naloxone sublingual film that are at issue in these trials.

Trials against Dr. Reddy's, Actavis and Par in the lawsuits involving the Orange Book and process patents occurred in November-December of 2015 and November of 2016. On June 3, 2016, the Court issued its Trial Opinion finding that the asserted claims of U.S. Patent No. 8,603,514 ("the '514 patent") are valid and infringed by Watson's and Par's ANDA Products. On August 31, 2017, the Court upheld the asserted U.S. Patent No. 8,900,497 ("the '497 patent") as valid but not infringed by Par's, Watson's or Dr. Reddy's proposed processes for making their ANDA Products. The Court also again upheld the validity of the '514 patent but held it was not infringed by Dr. Reddy's ANDA Products. All of these cases are

consolidated on appeal to the Federal Circuit. The trial against Alvogen was held in September 2017. The only issue raised at trial was whether Alvogen's ANDA Products and processes infringe the '514 patent and '497 patent; Alvogen did not challenge the validity of the patents. The Court has not yet issued an opinion in that case. If any company is able to obtain FDA approval for its generic version of Suboxone Sublingual Film, it may be able to launch the product prior to the expiration of any or all the applicable patents protecting our Suboxone Sublingual Film, which could have a material adverse effect on our business, prospects, results of operations and financial condition.

In 2016, the Company prevailed in ongoing litigated cases against certain competitors. On April 7, 2016, the USPTO upheld the validity of all challenged patent claims initiated by a competitor against certain key patents held by the Company. On June 3, 2016, the U.S. District Court of Delaware ruled that certain generic competitors have infringed on key patents held by the Company. This Court's ruling represents a barrier preventing generic formulations of Suboxone from entering the market prior to patent expiration in 2024. The ruling is subject to appeal. The Company continues to explore potential patent right enforcement actions against other competitors, particularly in the United States.

The Company is also seeking to enforce its patent rights in multiple cases against BioDelivery Sciences International, Inc. ("BDSI"). Two cases are currently pending but stayed in the Eastern District of North Carolina. The first was filed by the Company and Indivior related to BDSI's infringing Bunavail product, and alleges infringement of the Company's patent, U.S. Patent No. 8,765,167 ("the '167 patent"). This case was initially filed in September 2014 in the District of New Jersey but was transferred to North Carolina. Shortly after the case was filed, BDSI filed an IPR challenging the asserted '167 patent. On March 24, 2016, the Patent Trial and Appeal Board ("PTAB") issued a final written decision finding the '167 patent was not unpatentable. The North Carolina case is stayed pending the outcome and final determination of the proceedings concerning the '167 patent, which is currently on appeal to the Federal Circuit (discussed below). There is also a declaratory judgment action in North Carolina brought by BDSI for invalidity and non-infringement of the Company's U.S. Patents Nos. 7,897,080 ("the '080 patent"), 8,652,378 ("the '378 patent") and 8,475,832 ("the '832 patent"). The parties jointly moved the court for a stay of the proceeding pending *inter partes* review of the '832 patent and reexamination of the '080 patent. The case is currently stayed.

On January 13, 2017, the Company filed an additional claim against BDSI asserting infringement of the '167 patent by BDSI's Belbuca product. The case was transferred from New Jersey to the District of Delaware by agreement of the parties. BDSI has filed motions to dismiss and motions to transfer to the Eastern District of North Carolina. The Judge has not yet ruled on these motions. On November 28, 2016, BDSI filed a notice of appeal to the Federal Circuit of the PTAB's final written decisions finding that the '167 patent was not unpatentable in IPR2015-00165, IPR2015-00168 and IPR2015-00169. The case has been fully briefed and the Court heard oral arguments on February 9, 2018. Nothing further has occurred on this matter.

In September 2017, Indivior brought suit against Alvogen for infringement of U.S. Patent No. 9,687,454 ("the '454 patent") based on the filing of an ANDA seeking approval for a generic version of Suboxone Sublingual Film, in the U.S. District Court for the District of New Jersey. In February 2018, the Company and Indivior amended the complaint, which added it as a plaintiff and added a claim for infringement of U.S. Patent No. 9,855,221 ("the '221 patent").

Indivior brought suits against Dr. Reddy's and Teva in September 2017, and against Par and certain affiliates in October 2017, for infringement of the '454 patent, in the U.S. District Court for the District of New Jersey.

Indivior also brought suit in September 2017 against Actavis Laboratories UT, Inc. for infringement of the '454 patent, in the U.S. District Court for the District of Utah. On March 13, 2018, the Court granted transfer of this case to the U.S. District Court for the District of Delaware.

In February 2018, the Company and Indivior brought suit against Actavis, Dr. Reddy's, Teva, and Par and certain affiliates for infringement of the '221 patent. The suit against Actavis was filed in the U.S. District Court for the District of Utah, and the other three cases were filed in the U.S. District Court for the District of New Jersey.

The Company has also been named as a Defendant in a Complaint filed by 41 U.S. states and the District of Columbia, alleging violations of federal and state antitrust and consumer protection laws related to Suboxone Sublingual Film. The Court denied the Company's motion to dismiss on October 30, 2017. The case is in early stages of discovery.

From time to time, the Company may become involved in other various lawsuits and legal proceedings, the results of which are inherently unpredictable due to the uncertainties that must be resolved as these matters are adjudicated or settled. These legal actions arise in the ordinary course of business. Provisions for liabilities arising from these matters are made when it is both probable that a liability has been incurred and the amount of that liability can be reasonably estimated. Management is currently not aware of any such legal proceedings or claims against the Company that may have, individually or in the aggregate, a material adverse effect on the Company's business, financial condition, operating results, or liquidity.

The Company has defended, and is committed to prudently defending, its patent portfolio and rights. The patent defense expense were $4,759 and $4,791 for the years ended December 31, 2017 and 2016, respectively. These costs consist of fees incurred for the services of patent attorneys, litigation attorneys and certain other experts that may be required to protect the Company's patent rights against infringement from unlicensed users, including actions involving defense of patents during review and reexamination proceedings before the U.S. Patent and Trademark Office ("USPTO"), as well as those involving matters brought before U.S. Federal District or other courts.

(In thousands, except unit and per unit information)

15. Geographic Information

The Company manages its operations geographically as United States, Australia and Malaysia. The United States is the only country to contribute more than 10% of total revenue in 2017 and 2016.

The following table provides revenue by geographic area:

	For the Year Ended December 31,	
	2017	2016
United States	$ 63,840	$ 50,356
Australia	3,046	1,355
Malaysia	32	74
Revenues	$ 66,918	$ 51,785

The Company's long-lived assets are entirely located in the United States.

16. Redeemable Preferred Membership Interests

A. Redeemable Preferred Series A-3 Interests

A Private Placement Offering of Redeemable Preferred Series A-3 Interests (the "Series A-3 interests") was completed in December 2015 in the net amount of $5,038. The Series A-3 interests are senior to all membership interests with respect to dividends. In the event of additional issuances of certain equity interests at a price lower than specified minimum levels, the Series A-3 interests are to be adjusted to diminish the effects of resulting dilution. The Series A-3 interests are also provided with specified preemptive purchase rights, and further, in the event of a private placement or public offering, the Series A-3 interests may elect to convert their interests into the new offering. In the event of liquidation, holders of the Series A-3 interests will receive the greater of three times their original investment or 10% of any remaining distributable assets plus any accrued and unpaid dividends prior to any distributions to the Series A, Series A-1, Series A-2 or common holders, or senior common holders if any. On or after December 31, 2015, subject to the limitations of the current Loan Agreement that restrict dividend or other cash payments to specified preferred interests (Note 12), the holders of more than 50% of the outstanding A-3 interests, voting separately as a class, may require the Company to redeem all, or any part, of the Series A-3 interests at their original issue price plus accrued and unpaid dividends upon 60 days' notice out of funds legally available for distribution. As the redemption option is not within the control of the Company, the Series A-3 interests are classified outside of permanent equity on the consolidated balance sheets. These interests accrue a cumulative and compounding dividend of 8% per annum. At December 31, 2017 and 2016, accrued dividends totaled $858 and $420, respectively.

B. Redeemable Preferred Series A-2 Interests

A Private Placement Offering for $20,887 Redeemable Preferred Series A-2 Interests (the "Series A-2 interests") was completed in July 2008. The Series A-2 interests are senior to all membership interests other than those of the Series A-3 interests with respect to dividends. In the event of additional issuances of certain equity interests at a price lower than specified minimum levels, the Series A-2 interests are to be adjusted to diminish the effects of resulting dilution. Series A-2 interests are also provided with specified preemptive purchase rights. Upon liquidation, holders of the Series A-2 interests will receive two times their original investment plus any accrued and unpaid dividends prior to any distributions to the Series A, Series A-1, or common holders. Beginning after the fifth anniversary of the closing of the offering of the Series A-2 interests, subject to the limitations of the current Loan Agreement that restrict dividend or other cash payments to A-2 interests (Note 12), the holders of more than 50% of the outstanding Series A-2 interests, voting separately as a class, may require the Company to redeem

all, or any part, of the Series A-2 interests at their original issue price plus accrued and unpaid dividends upon 60 days' notice out of funds legally available for distribution. As the redemption option is not within the control of the Company, the Series A-2 interests are classified outside of permanent equity on the consolidated balance sheets. These interests accrue a cumulative and compounding dividend of 6% per annum. At December 31, 2017 and 2016, accrued dividends totaled $15,283 and $13,241, respectively.

17. Members' Equity

The preferred interests included in permanent equity are presented in the accompanying consolidated financial statements in order of liquidation preference.

The Series A interests rank senior to the Series A-1 interests and common interests with respect to payment of dividends and amounts due upon liquidation, dissolution, or winding up of the Company. The Series A-1 interests are senior to the common interests with respect to dividends and liquidation proceeds.

The Series A and A-1 interests hold the same voting rights and equivalent shares in the Company's earnings and losses as the common interests and any senior common interests that may be issued. In the event of an initial public offering or under certain other specified events, outstanding preferred, senior common and common interests in the Company may be converted into equity interests of the newly established public entity or merger partner relative to their then-existing equity account balances.

The Company is required to receive the written consent of more than 50% of the preferred interests prior to:

- liquidating, dissolving, or winding up the Company,
- amending or repealing the Limited Liability Company Agreement, or
- creating or authorizing a security senior to the preferred interests or increasing the authorized number of preferred interests.

During January 2017, White Oak Global Advisors, LLC, exercised its right to convert warrants, obtained as part of the 2013 financing transaction, into common membership interests. This warrant exercise resulted in an increase of membership interests of 2,443,249 and proceeds of approximately $24 to the Company.

18. Performance Unit Plans

The Company has two PUP Plans, both of which are considered to be within the scope of FASB ASC Subtopic 718-30, *Compensation – Stock Compensation – Awards Classified as Liabilities.* Pursuant to the Plans, vested grants may not be exercised prior to either a change in control of the Company or completion of an IPO. These performance conditions render the grants contingent and defer expense recognition until either of the conditions is satisfied.

Each performance unit granted represents the right to receive an amount equal to the increase in the fair value of a unit of membership interest in the Company from the date of grant to the date of settlement, all as determined by the Company's advisory board. For purposes of establishing the initial fair value of awards granted, the advisory board has in certain instances relied on third-party investments at or near the award date as the basis for estimating the underlying value of the Company. In instances where recent third-party investments, at or near the award date, are not available, the advisory board has measured the underlying value of the Company by utilizing an enterprise value approach, which takes into account the cash invested in the Company and outstanding debt at the time of grant.

In general, performance units awarded by the Company vest over time and have an indefinite contractual term, subject to continuing employment or other service with the Company. Vesting accelerates upon a change in control or IPO of the Company. The Company has the right to redeem

(In thousands, except unit and per unit information)

vested performance units within 12 months following a termination of the unit holder's employment or other service. Vested units can be settled for cash or equity interests of the Company or an acquiring or successor company, as the case may be, at the Company's discretion. However, the holder is not entitled to settlement of his or her vested performance units unless and until there is a change in control of the Company or the completion of an IPO. As of December 31, 2017 and 2016, respectively, there were 60,707 and 54,214 performance units outstanding that would be redeemable in the event either of the performance conditions were met. If these awards were to be cash settled based on the estimated enterprise value as of December 31, 2017, the Company's operating loss and net loss would have included an additional $12,870 in compensation expense.

Certain participants in the Plans, principally senior management, have been granted protection against dilution of their interests by future equity events (dilution protection). This protection survives the termination of the Plans and entitles the participant to receive additional shares of common stock to maintain the relative equity percentage held by the participant upon the occurrence of a dilutive event. As of December 31, 2017 and 2016, respectively, 24,677 and 21,989 of the outstanding units were covered by dilution protection.

Performance unit plan activity for the years ended December 31, 2017 and 2016 were as follows:

	Units	Weighted-average grant-date fair value	Weighted-average per unit base value	Aggregate settlement value[2]
Outstanding at December 31, 2015	55,773	$ 64,562	$ 0.26	$ 9,823
Granted[1]	431	114,941	0.47	—
Exercised	—	—	—	—
Forfeited/cancelled/expired	(1,989)	(103,276)	0.42	—
Outstanding at December 31, 2016	54,215	63,542	0.26	11,694
Granted[1]	6,561	113,298	0.46	—
Exercised	—	—	—	—
Forfeited/cancelled/expired	(69)	(106,718)	0.43	—
Outstanding at December 31, 2017	60,707	68,832	0.28	12,870
Vested at December 31, 2017	55,986	$ 65,023	$ 0.26	$ 12,688
Exercisable at December 31, 2017	—			

(1) Based on the estimated fair value of the Company on the grant dates of the performance units.

(2) Represents the estimated cash settlement value of these awards based on an independent third-party valuation in 2015 of $108,000 and enterprise values, which approximate fair value of $121,300 and $116,200 in 2017 and 2016, respectively, and the base values inherent in the underlying awards. Broadly viewed, settlement value is determined on the basis of a portion of the increase from the Company's fair value on grant dates to its fair value on the settlement date. The portion allocable to the PUP Plans is relative to vested performance units outstanding and actual equity interests outstanding.

During 2017 and 2016, no performance units were exercised, no share-based liabilities were recorded and 2,880 and 874 units vested, respectively.

MonoSol Rx, LLC

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

(In thousands, except unit and per unit information)

Activity in non-vested performance units for the years ended December 31, 2017 and 2016 were as follows:

	Units	Weighted-average grant-date fair value[1]	Weighted-average per unit base value
Nonvested at December 31, 2015	3,541	$ 103,070	$ 0.41
Granted	431	114,941	0.47
Vested	(874)	102,575	0.42
Forfeited/cancelled/expired	(1,989)	103,276	0.42
Nonvested at December 31, 2016	1,109	107,737	0.44
Granted	6,561	113,298	0.46
Vested	(2,880)	114,044	0.46
Forfeited/cancelled/expired	(69)	106,718	0.43
Nonvested at December 31, 2017	4,721	$ 111,131	$ 0.45

(1) Based on the estimated fair value of the Company on the grant dates of the performance units.

19. Employee Benefit Plans

The Company sponsors a defined-contribution 401(k) plan covering all full-time employees and makes matching employer contributions as defined by the terms of that plan. The Company may also make discretionary contributions. Total contributions made to the plan by the Company for the years ended December 31, 2017 and 2016 were $616 and $524, respectively.

20. Asset Retirement Obligations

The Company's ARO consists of estimated future spending related to removing certain leasehold improvements at its Portage, Indiana, laboratory, the Ameriplex production facility and the Warren, New Jersey, laboratory and returning all facilities to their original condition. Below is a schedule of activity in the Company's liability for AROs for the years ended December 31, 2017 and 2016:

Balance at December 31, 2015	$ 852
Accretion	107
Balance at December 31, 2016	959
Accretion	122
Balance at December 31, 2017	$ 1,081

Depreciation expense related to the ARO assets included in overall depreciation expense for the periods ended December 31, 2017 and 2016 were $25 and $26, respectively.

21. Income Taxes

From the period January 1, 2017 through October 31, 2017 and for all 2016, the Company was a limited liability company ("LLC") that passed through income and losses to its members for U.S. federal and state income tax purposes. From November 1, 2017 through December 31, 2017, the LLC elected to be taxed as a C corporation.

MonoSol Rx, LLC

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

(In thousands, except unit and per unit information)

The tax effect of temporary differences between the tax bases of assets and liabilities and their financial reporting amounts that give rise to the deferred tax assets and deferred tax liabilities at December 31, 2017 are as follows:

	December 31, 2017
Deferred tax assets:	
Accounts receivable	$ 14
Inventory	49
Accrued expenses	12
NOL carryforwards	1,330
Other	319
Property and equipment	1,145
Credits	113
	$ 2,982
Deferred tax liabilities:	
Intangible assets	$ (45)
Prepaid expenses	(148)
	(193)
Valuation Allowance	$ (2,789)
Net deferred tax asset/(liability)	$ —

At December 31, 2017, the Company had federal and state net operating loss carryforwards of approximately $9,900, which expire during 2038. The Company has determined, based upon available evidence that is more likely than not that the net deferred tax asset will not be realized and accordingly, has provided a full valuation allowance against its net deferred tax assets. Valuation allowances of approximately $2,800 have been established at December 31, 2017. The Company may also be subject to the net operating loss utilization provisions of Section 382 of the Internal Revenue Code. The effect of an ownership change would be the imposition of an annual limitation on the use of NOL carry forwards attributable to periods before the change. Although we have not completed an analysis under Section 382 of the Code, it is possible that the utilization of the NOLs will be limited.

Entities are also required to evaluate, measure, recognize and disclose any uncertain income tax provisions taken on their income tax returns. The Company has analyzed its tax positions and has concluded that as of December 31, 2017, there were no uncertain positions. The Company did not have any unrecognized tax benefits and has not accrued any interest or penalties through 2017.

A reconciliation of income tax benefit and the amount computed by applying the statutory federal income tax rate of 34% to loss before taxes for December 31, 2017 as follows:

	2017
Income taxes at statutory rate	34.00%
Increase (decrease) resulting from:	
State income tax	4.06
Permanent differences	(8.90)
Research & development credit	1.72
Valuation allowance	(13.54)
Effect of the deferred rate change	(17.34)
Effective tax rate	0.00%

The Tax Cuts and Jobs Act (the "TCJA") was signed into law on December 22, 2017. This tax reform legislation, which included a reduction in the U.S. Federal income tax rate from 34% to 21% resulted in a reduction of approximately $1,100 for the deferred tax assets related to net operating losses and other assets. This did not have a material impact on the Company's provision for income taxes for the year ended December 31, 2017 due to the valuation allowance against the Company's net deferred tax assets. Additionally, the Company does not expect to incur the deemed repatriation tax established by that legislation due to the aggregate cumulative losses of its foreign operations.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed in reasonable detail to complete the accounting for certain income tax effects of the TCJA. We did not identify items for which the income tax effects of the 2017 TCJA have not been completed and could not be reasonably estimated as of December 31, 2017, and as such, our financial results reflect the income tax effects of the TCJA for which the accounting under ASC Topic 740 is complete.

Should the Company have been treated as a taxable entity in 2016, no provision would have been recorded given the history of operating losses and the full valuation allowance which would have net against the deferred tax assets.

22. Subsequent Event

In preparing the consolidated financial statements as of and for the year ended December 31, 2017, the Company has evaluated subsequent events for recognition and measurement purposes through April 2, 2018, the date that the report of the independent registered public accounting firm was issued and the audited annual consolidated financial statements were available for issuance. The Company has concluded the following event requires disclosure in the accompanying consolidated financial statements:

Conversion to Corporation

On January 1, 2018, the Company converted from a Delaware limited liability company to a Delaware corporation and incorporated as Aquestive Therapeutics, Inc.

Shares

Aquestive Therapeutics, Inc.

Common Stock

PRELIMINARY PROSPECTUS

BMO Capital Markets

RBC Capital Markets

Wedbush PacGrow

JMP Securities

, 2018

Through and including , 2018 (25 days after the commencement of this offering), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

PART II
Information not required in prospectus

Item 13. *Other Expenses of Issuance and Distribution.*

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, payable by Aquestive Therapeutics, Inc., or the Registrant, in connection with the sale of the common stock being registered. All amounts shown are estimates except for the SEC registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the Nasdaq listing fee.

	Amount to be Paid
SEC registration fee	$ *
FINRA filing fee	*
Nasdaq listing fee	*
Blue sky qualification fees and expenses	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous expenses	*
Total	$ *

* To be completed by amendment.

Item 14. *Indemnification of Directors and Officers.*

The Registrant is incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law provides that a Delaware corporation may indemnify any persons who are, or are threatened to be made, parties to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person is or was an officer, director, employee or agent of such corporation, or is or was serving at the request of such person as an officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who are, or are threatened to be made, a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person is or was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses which such officer or director has actually and reasonably incurred. The Registrant's certificate of incorporation and bylaws provide for the indemnification of our directors and officers to the fullest extent permitted under the Delaware General Corporation Law.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability for any:

- transaction from which the director derives an improper personal benefit;

- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

The Registrant's certificate of incorporation includes such a provision. Expenses incurred by any officer or director in defending any such action, suit or proceeding in advance of its final disposition shall be paid by the Registrant upon delivery to the Registrant of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified by the Registrant.

As permitted by the Delaware General Corporation Law, the Registrant intends to enter into, indemnification agreements with its directors and executive officers. These agreements, among other things, will require the Registrant to indemnify each director and officer to the fullest extent permitted by law and advance expenses to each indemnitee in connection with any proceeding in which indemnification is available.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and the Registrant is not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

The Registrant has an insurance policy covering our officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, or otherwise.

The form of underwriting agreement will provide for indemnification by the underwriters named in this registration statement of our executive officers, directors and the Registrant, and by the Registrant of the underwriters named in this registration statement, for certain liabilities, including liabilities arising under the Securities Act, in connection with matters specifically provided in writing for inclusion in this registration statement.

Item 15. ***Recent sales of unregistered securities.***

The following sets forth information regarding all unregistered securities sold by the Registrant since January 1, 2015:

Series A-3 Preferred Interests Issuance

In December 2015, Aquestive, LLC, our parent and predecessor, issued 5,055,000 Series A-3 Preferred Interests to certain accredited investors for $5,055,000. The Series A-3 Preferred Interests contain a conversion option exercisable upon the offering, giving the holder the right to convert the interests into shares of our common stock.

Perceptive Warrants

In connection with the Credit Agreement and Guaranty we entered into with Perceptive Credit Opportunities Fund, LP, or Perceptive on August 16, 2016, we issued 11,625,437 warrants to purchase shares of our common stock representing 4.5% of our fully diluted common stock on an as converted basis. On January 1, 2018, in connection with our conversion into a Delaware corporation, we exchanged such warrants for new identical warrants that were immediately exercisable upon issuance into shares of our common stock at an exercise price of $0.01 per share. The warrants issued to Perceptive expire on August 16, 2023 and are subject to anti-dilution adjustments so that, upon exercise, they will represent 4.5% of our fully diluted common stock on an as converted basis.

PUP Plan Issuances

The PUP Plans of Aquestive, LLC are expected to be terminated in April 2018, effective as of January 1, 2018. Upon termination of the PUP Plans and in lieu of cash, we plan to pay the equivalent value in shares of our common stock. Shares of common stock are expected to be issued to directors, officers and key employees in the following amounts:

Keith J. Kendall	12,338,405
Daniel Barber	1,221,000
Peter Boyd	610,000
John T. Maxwell	1,710,274
A. Mark Schobel	12,338,405
Theresa Wood	978,000
Douglas Bratton	926,421
Gregory Brown, M.D.	926,421
John Cochran	926,426
Santo Costa	213,789
James S. Scibetta	71,263

The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about the Registrant.

Unless otherwise stated, the sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act (or Regulation D promulgated thereunder), or Rule 701 promulgated under Section 3(b) of the Securities Act in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701.

Item 16. ***Exhibits and financial statement schedules***.

(a) Exhibits

See the Exhibit Index attached to this Registration Statement, which is incorporated by reference herein.

(b) Financial statement schedules

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the consolidated financial statements or notes thereto.

Item 17. ***Undertakings***.

The undersigned Registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

EXHIBIT INDEX

Exhibit Number	Exhibit Description
1.1*	Form of Underwriting Agreement.
3.1*	Certificate of Incorporation, as currently in effect.
3.2*	Form of Amended and Restated Certificate of Incorporation, to be in effect upon consummation of this offering.
3.3*	Bylaws, as currently in effect.
3.4*	Form of Amended and Restated Bylaws, to be in effect upon consummation of this offering.
4.1*	Form of Common Stock Certificate of the Registrant.
4.2*	Warrant to Purchase 11,625,437 senior common equity interests to Perceptive Credit Opportunities Fund, LP, dated as of August 16, 2016.
5.1*	Opinion of Dechert LLP.
10.1*	Form of Indemnity Agreement by and between Registrant and its directors and officers.
10.2*	Credit Agreement and Guaranty dated August 16, 2016, by and between Monosol Rx, LLC and Perceptive Credit Opportunities Fund, LP.
10.3*	Employment Agreement dated November 17, 2008, by and between Monosol Rx, LLC and Keith Kendall.
10.4*	Employment Agreement dated November 17, 2008, by and between Monosol Rx, LLC and A. Mark Schobel.
10.5*	Employment Agreement dated January 9, 2017, by and between Monosol Rx, LLC and John Maxwell.
10.6†*	Commercial Exploitation Agreement by and between MonoSol Rx, LLC and Reckitt Benckiser Pharmaceuticals Inc., dated August 15, 2008 (as amended on August 19, 2009, November 13, 2009, March 30, 2010, October 13, 2010, December 15, 2010, December 9, 2011, December 1, 2012, October 14, 2013 (by Addendum A), July 30, 2014 (by Addendum B), and January 12, 2017.
10.7†*	Agreement by and between MonoSol Rx, LLC and Indivior UK Limited, dated September 24, 2017.
10.8†*	Agreement to Terminate CLA by and between MonoSol Rx, LLC and KemPharm, Inc., dated as of March 20, 2012.
10.9†*	License Agreement by and between MonoSol Rx, LLC and Cynapsus Therapeutics Inc., dated as of April 1, 2016.
10.10*	Industrial Lease Agreement by and between Ashland Northwest Partners, L.P. and MonoSol Rx, LLC, dated October 24, 2006 (as amended on October 24, 2011 and February 8, 2018).
10.11*	Aquestive Therapeutics, Inc., 2018 Equity Incentive Plan and forms of agreement thereunder.
23.1*	Consent of KPMG LLP, Independent Registered Public Accounting Firm.
23.2*	Consent of Dechert LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (see signature page of the original filing of this registration statement).

* To be filed by amendment.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment that will be separately filed with the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the County of Somerset, State of New Jersey, on the day of , 2018.

Aquestive Therapeutics, Inc.

By:

Keith J. Kendall
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Keith J. Kendall and John T. Maxwell, as his true and lawful attorney-in-fact and agent, with the full power of substitution, for him and in his name, place or stead, in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments), and to sign any registration statement for the same offering covered by this registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
Keith J. Kendall	President, Chief Executive Officer and Member of the Board of Directors (Principal Executive Officer)	, 2018
John T. Maxwell	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	, 2018
Douglas Bratton	Chairman of the Board of Directors	, 2018
Gregory Brown, M.D.	Member of the Board of Directors	, 2018
John Cochran	Member of the Board of Directors	, 2018
Santo Costa	Member of the Board of Directors	, 2018
James S. Scibetta	Member of the Board of Directors	, 2018
A. Mark Schobel	Member of the Board of Directors	, 2018